HIT Policy Committee
Final Transcript
October 20, 2010

Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director
Good morning, everybody, and welcome to the 17th meeting of the HIT Policy Committee. Again, this is a federal advisory committee, and we will allow public comment at the close of the meeting, and there will be a transcript on the ONC Website. Just a reminder for members around the table to please identify yourselves when speaking.

Let's go around the table now and introduce yourselves beginning on my right with Jodi Daniel.

Jodi Daniel – ONC – Director Office of Policy & Research
Jodi Daniel, ONC.

Latanya Sweeney – Laboratory for International Data Privacy – Director
Latanya Sweeney, Harvard University.

Marc Probst – Intermountain Healthcare – CIO
Marc Probst with Intermountain Healthcare.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
Larry Wolf for Rick Chapman, Kindred Healthcare.

David Lansky – Pacific Business Group on Health – President & CEO
David Lansky, Pacific Business Group on Health.

David Blumenthal – Department of HHS – National Coordinator for Health IT
David Blumenthal, ONC.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Paul Tang, Palo Alto Medical Foundation.

David Bates – Brigham and Women's Hospital – Chief, Div. Internal Medicine
David Bates, Brigham and Women's and Harvard.

Paul Egerman – Software Entrepreneur
Paul Egerman, software entrepreneur.

Judy Faulkner – Epic Systems – Founder
Judy Faulkner, Epic.

Jim Borland – SSA – Special Advisor for Health IT, Office of the Commissioner
Jim Borland, Social Security Administration.

Christine Bechtel – National Partnership for Women & Families – VP
Christine Bechtel, National Partnership for Women and Families.

Deven McGraw – Center for Democracy & Technology – Director
Deven McGraw, Center for Democracy and Technology.

Tony Trenkle – CMS – Director of OESS
Tony Trenkle, CMS.

Judy Sparrow – Office of the National Coordinator – Executive Director
Are there any members on the telephone? If not, I'll turn it over to Dr. Blumenthal.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Thanks to members of the committee, the audience, and folks here virtually. This is one of obviously many meetings. I think we have now, in the last 18 months, exceeded 200 meetings of our policy committees, Standards Committee, and their workgroups. I don't want to do the arithmetic to try to estimate how many meetings that means a week, but Judy Sparrow undoubtedly knows, and I'm sure it keeps her up at night.

This is a very important meeting. It sort of begins a next phase in the Policy Committee's work and has us pointing again toward the future and another stage in the work of the Office of the National Coordinator, the administration, and this group. We're going to begin talking today about the next stages of meaningful use. Now for those of you who are involved in trying to react to the first stage of meaningful use, we want to reassure you that we are not already changing meaningful use and creating new targets that you already have to adjust to.

We are mindful of the fact that the first go around was very rushed. We had to create conceptual frameworks, positive measures, react to them quickly, make recommendations from this committee, pass them on to the Standards Committee, and do that all in a very, very tight timeframe that didn't leave us time for a lot of reflection, a lot of careful forward planning. We want to do better than that this time, or I think we did as well as we could, but we want to make sure that we have more time to think about our longer-range strategy. We're going to begin talking today at a more conceptual level about how we want to think about the next stages of meaningful use, whether they're sort of linear continuations of the first stage or whether they are, in some ways, will lead us in somewhat different paths.

There's certainly a lot to discuss, not only at the conceptual level, but at a more practical level. But I do hope that we will, at this point, think more about the strategy than we will about specific measures. I know that the Meaningful Use Workgroup has done a lot of thinking about specific measures. But I think that thinking should be kept in reserve for a little while, as we take a larger perspective.

We're also mindful that we do need to inform later stages of meaningful use with the experience of the first stage of meaningful use. There will be time to learn about how providers in the public and other stakeholders are affected by and are reacting to stage one before we regulate on stages two and three. But the effort, the reason for getting to this topic now rather than waiting six months is precisely so that the conversation is not more rushed than it has to be.

There are also some other very important issues that remain on our table that are relevant to stage one, very relevant to stage one of meaningful use. One of these is how to keep moving forward on creating the infrastructure for health information exchange. Meaningful use stage one focused predominantly on adoption and meaningful use by providers of care within their own practices and organizations. We've said in the preamble to stage one that later stages of meaningful use would talk a great deal more about information exchange.

But there also is the obligation in stage one to maximize the opportunity for those who are capable of exchange to do so. Related, we need to continue to the excellent work of the Privacy and Security Tiger Team on protecting information, both at rest and in transit, so that the public has confidence and trust in the health system's ability to steward their health information capably. There are other issues related to quality and related to the governance of health information exchange that will also be on the agenda

today, but I wanted to make these opening remarks just to give us some thoughts about where we are in the discussion, the many discussions we're having, and also what the priorities are in the short-term.

I want to say that I've been on the road a great deal over the last couple months. I won't bore you with all my destinations, all my visits. In the last week, I've been in Austin, Chicago, and Boston. Actually, the last four days. I'll be on the road more in the next month or so. We've been visiting with medical associations, hospital associations, grantees of our office regional extension centers, health information exchange groups, state legislators, representatives of governors, and there is a great deal of activity, interest, even in some places enthusiasm, but also a lot of appropriate sort of worry about how to respond to all the things we've already done in the last 18 months or so. We will be continuing to try to collect that kind of intelligence through the Office of the National Coordinator, and I hope that members of this group will also do the same.

I want to point out that the Center for Medicare and Medicaid Services, Tony Trenkle and his group, have been very, very busy responding to queries or questions about stage one meaningful use. Frequently asked questions are already up on their Website and our Website, and we expect to continue to get them. The questions are very helpful, and inevitable and important clarifying questions for new and important new regulations of this type. I don't know, Tony, if you want to add anything at this point.

Tony Trenkle – CMS – Director of OESS
There are a couple documents, as I mentioned, in the Meaningful Use Workgroup. They're now in the clearance process. One is the corrections notice from our regulation that will correct some errors that were in there that you'd expect in a large publication like that. The other is the detailed specifications of the objectives that are also in a clearance process, but we hope to have put on our Website soon. We now have 106 FAQs up on the Website. We're revising the Website to make it more easier to sort and also working closely with ONC so that we can have a joint presentation to the public. As David said, we hope to continue to get questions and clarification queries because that helps not only produce a better product, but it also would help us, as we move towards future regulation publications to help clarify things that maybe we didn't clarify as well as we should have.

David Blumenthal – Department of HHS – National Coordinator for Health IT
With that, I'm going to turn to Paul for a run of the agenda, and then he'll introduce himself as the first, he and George Hripcsak as the first item on the agenda.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
The agenda reflects the number of busy activities that are going on in ONC and CMS and the various workgroups, as we speak. Two hundred meetings sounds like a lot and it feels like a lot.

As David mentioned, we're focusing a lot on the future stages, that's stage two and stage three. There are accompanying kinds of proposals such as the quality measures, so we're going to open up talking about where we are with stage two, the stage two and stage three development process in the Meaningful Use Workgroup. Really this is, as David said, an open discussion about some of the philosophical approaches, as we go towards those future stages. So we're spending a fair amount of time with that topic.

In a related topic, there is the Quality Measures Workgroup, which has been working on, in a fast track mode with a number of tiger teams on trying to come up with quality measures that focus in on that end goal of measuring and improving outcomes, and we're going to hear an update from the various groups in that workgroup. Then continue on after lunch on the Information Exchange Workgroup, talking specifically about provider directories, and the next topic is privacy and security. We're going to hear about recommendations on transparency and conclude with an update from the NHIN Workgroup on governance. That's going to be presented by John Lumpkin. Then, finally, we'll have public comments before we adjourn.

That's the agenda for today. It's packed, but it sort of matches the activities that are going on in the department. Questions with that? If not, we'll begin the next section, which is the Meaningful Use Workgroup update.

For this section, we'll talk about where we've been and where we're headed with the Meaningful Use Workgroup discussion. George Hripcsak is the co-chair of the group, and this is a reminder of the people who sit on the workgroup. For today, we want to begin with a quick recap of how we got to stage one, what was the fast track recommendation process we undertook over a year ago. Talk to you about the pathway we've set for ourselves, the process for working on stage two, and then open it up for a series of directional kinds of strategies, discussion points for this full committee. There are still several months ahead of us in terms of opportunities for input, not only from this committee, but from other workgroups and the public. I'll be talking about that kind of at the end.

Let me recap for you what we went through in stage one. The HITECH legislation was passed in February of 2009. The office was set up in statute, and David Blumenthal was appointed probably in March or April of last year. Before this group was even formed, meaning the HIT Policy Committee, which as you know is the statutory FACA Committee, David started out the process of starting to understand meaningful use because the timelines were so tight. He took advantage of another FACA group, the NCVHS, who he asked to hold a hearing, which happened at the end of April, even before this group was constituted, to begin that discussion of meaningful use.

We had our first meeting of the HIT Policy Committee May 11th, and the Meaningful Use Workgroup was assembled May 28th. Within three weeks, which is the timeline David just referred to, we came out with that sort of blue matrix, which set up a framework with particular attention to the stage one requirements and some placeholders for stage two and three.

We got your feedback at the June 16th meeting. We incorporated that feedback, and then sent that out for a rather quick turnaround time for public comments and got about 800 comments to that particular draft recommendations. We revised our recommendations and then brought it back to this committee for July. You approved that with some minor changes, which we incorporated into the final recommendations from this committee to ONC and to CMS. CMS put out its NPRM January 13th. Then six months later, after getting 2,000 comments from the public and reacting to those, put out its final rule on July 13th. That's where we stand with stage one.

Fortunately, we've had more than three weeks to process, to take more input in about stages two and three. Over this past year, we've had a number of hearings, concentrating on topics such as hearing from the specialists, who we didn't pay as much attention to in formulating stage one. There were fewer, for example, quality measures that applied to specialists, so we got a chance to hear from them. We also concentrated on smaller practices and smaller hospitals, whether it's community hospitals or rural hospitals. Looked at state issues, had a panel on healthcare disparities, and tried to understand how can we better characterize that so that we can understand them and try to address the disparities that exist today.

Had a hearing on patient and family engagement, one on population and public health, and concluded our series of hearings with one on care coordination. All of these were extremely informative, and we're bringing that information into the process of looking towards stages two and three. Then taking the CMS final rule on stage one as the starting point and the ONC rule on EHR certification, we're working toward stages two and three, and we had a face-to-face meeting and a couple calls since. That's the point at which we would like to raise some issues that are directional. They may be a branch point. They're sort of philosophical issues about how to approach stages two and three. We'd like to open up for your discussion.

I'll introduce the topics here in an overview, and then we'll drill down on each of these and open it up for committee discussion. One is, as David was talking about, how do we position stage two? Is it the next

step from stage one, or is it a stepping-stone to stage three? You work from stage one in increment, or do you set up what we would like to have happen in stage three, which is 2015, and then have stage two as a checkpoint on the way to stage three?

Another topic is the whole notion, we have always positioned, and it was even positioned in the statute that this is a program not about installing software, but about measuring and improving our outcomes for individual health and the population health. What would state three look like if it is outcomes based? If that is going to be much more outcomes based, we should start introducing the notion of achieving higher outcomes with stage two, and we'll have a couple seed points for discussion.

Patient engagement, as you know, is one of the attributes we've brought into the discussion of meaningful use with the initial framework saying that it's not just about providers. It's really, if we're going to put health information in electronic form, we want patients to be able to take advantage of that and the market to be able to help patients make better use of that information. We know there are terms like access, copy, and clinical summaries in the rule. We tried to organize that, and we'll share with you some of our current thinking and get the benefit of your input as well.

Finally, this is happening not in a vacuum. Even after the passage of HITECH or the stimulus bill, we all know that the health insurance reform bill, the Affordability Care Act was passed. As an example, one of the organizational constructs put into there for future Medicare programs is the ACOs, the Accountable Care Organization. All these things depend on information and depend on HITs to some extent. Wouldn't it be nice if they all interrelated, if there was a way to harmonize these kinds of concepts and requirements? We'll talk about that as well.

Let me begin with the discussion about the positioning of stage two. As I mentioned, one approach is you take stage one, and you add something. You change the threshold, or you add more functionality to something, and increment to get stage two. The other way is to look at what would we like the program to finish with in 2015 with stage three, and then make stage two a stepping-stone.

The pros and the cons for incrementing over stage one, the pro you might consider to be we know what stage one is. If we take something we know and just make it more stringent or add more functionality, people would know how to deal with it. The con is that if you go from stage one, and then you specify stage two, you still have no clue what stage three is going to look like. That uncertainty, we've certainly heard from the market, is one that frustrates a number of people.

If we take the other approach and say, let's concentrate on stage three, and then make stage two a stepping-stone, the pro is that you do achieve one of the goals we had, which is to establish a roadmap and somewhat of a timeline, so this is where we're going to go in 2015. Everyone can orient at least their sights. Even though they don't have a final rule for 2015, they can organize their plans for develop of these projects or for implementing these products in the healthcare provider organizations. Frankly, I'm not sure that there are many cons that we can think of.

This is probably an approach that the workgroup thought was a more sensible approach, but we'd like to pause and get your input about that. Let me pause on this particular discussion topic. Hopefully this is just the warm up ones for things that are more potentially controversial in the next discussion topics. But let me open it up for comments now.

Paul Egerman – Software Entrepreneur

I have a couple of comments. First, on the issue of establishing a roadmap, it's certainly a good concept. I just want to point out, when we did stage one, we did also signal a number of things to people, and a lot of vendors, a lot of people look at what we do very carefully. It seems like, in stage two, we need to make sure that we visit everything that we signaled in stage one to make sure that we're doing that. Otherwise there's no— People aren't going to trust our roadmaps. Is that going to be part of stage two?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Yes, and I think it's almost a missing slide, so thanks for bringing up that question. What we took as our input going into this process are, one, the original matrix: One: The final rule, so that's the final rule on stage one requirements and criteria. Two: We looked at the original blue matrix, which had placeholders for stage two and three, so that's "original" draft roadmap. Yes, in fact, that was an important input to our process. Three: We took in all of the recommendations and summaries from the hearings that I mentioned along the way, and then considered all the other kinds of public input we've had through this whole process.

Yes, we had a summary table or matrix that included what we put on our original roadmap. We compared that to the new things we heard in the hearings, and then came up with a draft. We're working on a draft of what might be our recommendations back to this organization.

Paul Egerman – Software Entrepreneur
The other comment I have picks up on what Dr. Blumenthal said in his opening comments about information exchange and privacy. It seems to me that for stage two, if we did sort of an incremental change, incremental step from stage one, one of the things we could emphasize in stage two would be information exchange, privacy and security. That those are very good things to do in stage two, mainly because advancing those areas don't require a lot of training and workflow changes on the part of clinicians. They're more limited, and it seems like that's a very good place to put that in stage two is sort of like a bridge between stage one and stage three. There's going to be a lot of signaling, so I'd like to see stage two have some emphasis on information exchange and privacy and security as what we're trying to accomplish.

David Bates – Brigham and Women's Hospital – Chief, Div. Internal Medicine
With respect to incremental change versus the stepping-stone, I don't see the two as mutually exclusive. I would hope we could do some of each. I think they should certainly be a stepping-stone. To the extent that we can, I think we've heard clearly from the vendors and from the providers that they want to know where stage three is going to be. If we can make some statements about that, I think that will be positively received.

It seems to me that one way that we might begin to do this is to start to think in a reasonably careful way about what the 2015 goalposts will be. I do like the idea of being able to make midcourse adjustments based on how the market is actually doing. Perhaps one way that we could do that is that we could move the threshold. Once you actually get the incentives based on how far people have gotten, but we would have established the goals.

Judy Faulkner – Epic Systems – Founder
I wonder, Paul, if you could, as we talk about this, tell us the dates for everything. I know that we have some packets of information on that, but if you could repeat when each thing is coming up, I think this helps us put it into perspective of what the challenges will be in implementing this.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
The dates for the rule?

Judy Faulkner – Epic Systems – Founder
The signaling, the proposed rules, the final rules, the testing, and when it has to then be implemented in order to get full credit.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
It looks like Tony is ready to step in here and … final rule point of rule.

Tony Trenkle – CMS – Director of OESS

Judy, we're still looking at the possible dates for the rulemaking. We haven't finalized that at this point. It actually gets into a couple of the issues that I just wanted to bring up for Paul's attention, some of which you and I have talked about already, Paul, but one is the feedback loop. What are some of the thoughts that the committee might have on the best way we can get feedback, so we can begin to integrate it into future rulemaking. Of course, that also ties back into when you decide to do the timing for the rulemaking.

The second, Paul brought up the issue about signaling. I think one of the areas that we would certainly be interested in from a CMS perspective, but I think, also, ONC as well is one of the signaling areas was administrative transactions and the question of how do we begin to look at how that's going to impact not only the work that's being done through the Affordable Care Act, but also the ICD-10, the 5010, and some of the other major administrative transaction activities that are going on.

You mentioned the alignment. I think that's a critical area, not only to be coordinated in terms of driving towards the same goals, but also to make sure that they're not actually creating a disconnect that actually serves as inhibitors against each other. For example, if there's an area within the accountable care organizations criteria that might not be in synch with meaningful use, that's something that we need to look at and vice versa.

Then, finally, as we're looking at staging, the whole issue of Medicare and Medicaid, we try to align them as much as possible in stage one, but there are very key differences, not only in the populations, the provider groups that are eligible, the penalty phase in Medicare, the adopt, implement, and upgrade part of Medicaid, so they won't even be getting feedback on how well they're doing meaningful use until 2012. Those are the kinds of things, as we move along the trail, the meaningful use compendium, what types of linkages do we want to maintain, and then what types really need to be looked at from a separate standpoint.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
David, I can try to address Judy's question about the timing, at least as we talked about it in previous discussions. I think the anticipated timeline for the final rules for subsequent stages is approximately like we had with stage one. In other words, the NPRM came out in December or in January of 2010 for stage one that begins in 2011. So if you fast-forward that by two years, then for 2013, that would be something like January of 2012. That's partly determined by the clearance process and the NPRM process, but also, as everybody has been pointing out, waiting to get feedback from the previous stage before you move into the next stage.

I know that when we talked about the timelines during the recommendations, the NPRM stage and the final rule, that the industry and that's both the vendor side and the provider side, would like to have as much notice as possible. Yet we're sort of stuck between wanting to have notice, but not wanting to ignore how are we doing so far. That's why we got squeezed, and then you have the clearance process. That's how we go squeezed and weren't really able to deliver a final rule with the 18-month notice, but the compromise I think we struck up was the final rule process has a process that it needs to go through, and it has a certain amount of time. But what the HIT Policy Committee is trying to do is provide as much guidance and signaling as it can still waiting for updates from what is happening with the current stage. That would mean we would get our recommendations. The earliest would be the summer of 2011 because we just won't get any information until May at the earliest. That would give the 18 months from that signaling timeframe.

Judy Faulkner – Epic Systems – Founder
Paul, if it comes out at the same time, for stage one it didn't have to be implemented by the hospitals until July. My notes say that it now has to be implemented in January for the hospitals, which is going to be six months earlier. Is that correct or not correct? If so, that's a very short timeline in between to cut off those six months.

Tony Trenkle – CMS – Director of OESS
Could you explain further what you mean, January of when and …?

Judy Faulkner – Epic Systems – Founder
Yes. That's what I'm trying to figure out here.

M
January of 2011?

Judy Faulkner – Epic Systems – Founder
January of 2012.

Paul Egerman – Software Entrepreneur
It's 2013.

Judy Faulkner – Epic Systems – Founder
Yes, 2013.

Paul Egerman – Software Entrepreneur
January of 2013.

Judy Faulkner – Epic Systems – Founder
If in fact the final rules are out about the same time, but move it two years, if the hospitals have to start installing it January of 2013, whereas before they had until July of 2011, we're going to get into a crunch there.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
I think you're making ….

Judy Faulkner – Epic Systems – Founder
Or am I wrong in that assumption?

Tony Trenkle – CMS – Director of OESS
They could begin registering for the program for stage two or whatever we end up qualifying for the next stage of the program of October of 2012 because the hospitals run on the fiscal year, as opposed to the calendar year, for the EPs.

Judy Faulkner – Epic Systems – Founder
But to get the full credit from this, do they have to start in with those versions by January or not, January 2013, and run it for that full time or not?

David Blumenthal – Department of HHS – National Coordinator for Health IT
One way to think about this is to compare the timeframe we had to deal with in stage one with the timeframe we have in stage two. At this point in stage one, I hadn't been appointed. ONC hadn't been created … and you didn't exist as a committee. We didn't meet for stage one until May of this year, May of next year. If our first meeting to prepare for stage two were in May of 2011, that would be the equivalent timing for stage two to stage one. Do you follow what I'm saying? The point is that we actually have a good six months more to work on stage two than we had on stage one. Otherwise, the timing is analogous.

Judy Faulkner – Epic Systems – Founder
If we have six months more, than can we give more, move the proposed rule and the final rules and the testing rules earlier so that there's more time?

David Blumenthal – Department of HHS – National Coordinator for Health IT
We could, except that would then eliminate the chance to get feedback from the implementation of stage one.

Judy Faulkner – Epic Systems – Founder
Here are some of the reasons that we're saying this. When we looked at some of the signaling to the final, there are differences, examples. Regarding smoking status looks okay, but then when the details come out later on, then that caused close to 1,000 hours, 700 actually to implement that because it has to be done in multiple versions. Then bigger things were things such as exchange clinical information, which again looks like it's quite doable in the final proposed standards that came out. Then it was that there are two standards to exchange, which is different than the signaling, but it takes a lot of extra work. The question is, if these things fine-tune later, sometimes people may not understand how much programming it takes, and then it's going to make it difficult for the users to get it up and installed.

David Blumenthal – Department of HHS – National Coordinator for Health IT
You're making the general point that the sooner we can do it, the better.

Judy Faulkner – Epic Systems – Founder
Yes. Several points: The sooner the better. There was another one like reporting quality measures when the details came out on that. That took about 8,500 hours. The point is sooner and then is there some way either to get the specificity in earlier or later on to leave it more general and not be as specific depending on what the impact will be. Then I think another thing is when the testing comes out, is there a way that the testing can be reviewed to see whether the testing matches what the intent is for that.

I think that there are two things. One is this committee, and does the testing match that. Then the final rules, which isn't this committee, as this committee is just an advisory committee, and does the testing match what that was desired? Because there may be some differences in here were the tests, but here's what was intended. Paul, do you have any comments on that one?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
I think we're in the same rock and a hard spot that HHS is in, in the sense of, let's put in a different rock. Health reform is driven by a number of things going on in the environment. It's the cost of care. It's the fact that we can't deliver even the kind of care that we would like. There's sort of a rock sitting out there, or it's a brick wall that's sitting out there. We have to meet that no matter whether there was or wasn't, is or isn't a HITECH.

The fact that HITECH is responding to that same brick wall means that it has very aggressive timelines. I think, as a community in general, whether it's the vendors or the providers, we have to react to that brick wall that we face. This is a program that I'd almost look at as an extra incentive to get our house in order so that we can do a better job of maintaining the health of the population.

Judy Faulkner – Epic Systems – Founder
But what I've heard people say is if in fact it's so easy that everyone can do it, that's too easy. If it's so hard that few can do it, it's too hard. How do you find that middle spot?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
That's the tension we operate on from day one when we started working on this whole framework and putting in some things at certain mileposts. That's the tension we face. We're looking for one. We have some survey data on whether organizations think they can meet the final rule for stage one, and I'm actually somewhat encouraged by that, to tell you the truth. Then we need to see some hard data, and that's what we're waiting for is the industry's response to stage one, as they apply for it.

Judy Faulkner – Epic Systems – Founder

I guess what I'm saying is that if in fact stage one will be repeated at stage two in the same way, it's going to be a tremendous crunch for the vendors to get that development done and even a greater crunch for the healthcare organizations to get it installed by the dates required.

David Blumenthal – Department of HHS – National Coordinator for Health IT
I guess the best we can say is that we want to work with you to try to make whatever we do as feasible as possible.

Judy Faulkner – Epic Systems – Founder
Yes, because if it isn't feasible, then it doesn't make sense to … too idealistic.

Marc Probst – Intermountain Healthcare – CIO
Thanks for facilitating this conversation. It really is a great time to do it. First of all, I'd like to reiterate what David said. I don't think they're mutually exclusive at all, and I would hope that when we do set that stage, which is the right thing to do, let us know where to go. It builds off of incrementally what we're already doing in stage one.

The environment has changed. I'm going to Paul's comment that we set out there a framework early on, and we did it really quickly and amazingly well. I think the level of detail is terrific, but not everything. Much as changed from that time, and I think we have a lot to learn from the people that are actually doing the implementation. I've seen some of the survey data. Some of it is suspect to me. I've seen the CHIME data. CHIME in and of itself assumes that they have a CIO, which would guess to me they're already involved in technology, and there are many that aren't involved in CHIME that may have a very different perspective of what we're doing.

So I think we really do need to get a lot of feedback to drive what we're going to try and do in stage two and three. I'm thinking, just from the peers that I have, that we might be pretty surprised as to what people think can be accomplished in stage two and three. I very much back what Judy is saying. We need time to react to that. I'm happy the vendors have to react because when we receive it from the vendors, there's a tremendous amount of work to do because all of our environments are different. We can't just take Judy's software and say we can just plug it in; everything works. It's going to take us time.

ICD-10 has crept up to be real. I saw the ONC statistics on how many people have paid attention to it. I can tell you from myself and my peers, we haven't until recently. The experience at Intermountain Healthcare in just information systems alone to be prepared for 2013 is going to be about $8 million worth of effort in remediating and testing information systems, plus all the organizational change, which dwarfs what we're trying to do on the technology side.

I guess my comments are, I do really think we need to set that final stage. I don't know how locked in we are to timeframes. I doubt we are legislatively locked into timeframes. I think we have put some expectations out there. But if the opportunity exists to look at our timeframes that we put out there and they are changeable, I just know from personal experience, this is the bar right now is adequately high. It's going to be a challenge to accomplish everything that's being put out there when you put it in the environment of all the other change that's being asked for healthcare.

I think, on the ACO concept in building that in, it kind of goes back to even the current rules. Tony, you mentioned that there's going to be some clarifications that come out.

Tony Trenkle – CMS – Director of OESS
Right.

Marc Probst – Intermountain Healthcare – CIO
What's happening is there's continued clarification. Because there's even a nuance, a small change, we've basically stopped. We don't move because the code is so specific to what we have to do. So until

it's locked down, until we absolutely know what we have to accomplish, we pretty much have to stop. It's not like we don't have 150,000 other things to work on, so we go work on them, waiting for that firm stake in the ground that this is what we're going to do. Again, I guess it goes to stage three being really clear as to what we expect, and then being really firm. What are we going to test, as Judy suggests, and will those tests work? Are they explicit? Otherwise we're just going to have to focus on other things. So it is a very challenging time, and I appreciate you having that conversation and at least listening to those points.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
Let me begin by repeating what's been very quickly. Thank you all around for the context that's been set here. We are trying to take on some big changes. It took us a very long time to get to the 5%, 10%, 15% adoption we currently have. We're trying to squeeze an awful lot of change into a very short timeline. I think it's really important that we actually look at the whole of that timeline, so I know at the end of this, Paul and George, you've put together an outline of what it will take to get to the final rule.

I think it would be really good to extend that timeline in all of our planning. Even though the timing may be unknown, to include the milestones that would come after that. So after that, we would have certification because we have the criteria. After that, we would have product available for testing and implementation. After that, we'd have providers able to implement the product, train staff. After staff get trained, it takes time to see what's happening inside an organization, so if we're moving towards outcomes based measures, we need to see what our outcomes are, establish a baseline, look at our process, start to make changes, see what's working, see what's not working, so that too has its timeline.

I don't mean to say this in a pessimistic way. I actually mean it in an optimistic way. We're taking on a huge, wonderful change, and we're putting in place some very key infrastructure. I think we want to encourage innovation. We don't want to stifle innovation, and to sort of juggle these things of creating clear infrastructure requirements so people get the systems they need, plenty of roadmap to get to where we're going, and then the ability to actually handle.

The process changes are huge. People have sort of made light of the interconnect issues don't really change very much. They actually change a huge amount because today providers don't have the experience of live data to make a decision with. They need to change their thought process. They need to figure out how to go from a lack of data to an overwhelming amount of data. Not just some meds that the patient told me about, but the last five years of every med the patient ever took or ever was prescribed, and sorting out that morass.

I guess, to sort of cut to the chase here, this is complicated. We should take the time to be thoughtful. I think if in the next short while we can actually lay out the key principles that we're going to be acting under, that would be a really great thing to help clarify this. Then to consider extending the stage one time so that there's actually time to get the next stage right and time for people to implement it, time to get the feedback, and maybe not be locked into our notion of stage two and three as being separate, but maybe two and three become a combined goal.

Latanya Sweeney – Laboratory for International Data Privacy – Director
First of all, I want to just say that I always have felt that the meaningful use criteria, the way it's set up as policies and incentives structure, is absolutely the best work that has come out of ONC. Just absolutely, it's really great, the idea of having a carrot and having people move towards it. I have tremendous sympathy for you, Marc, and for you, Judy. As a computer scientist, having brought many products to market, I can tell you, I feel your pain.

But, at the same time, I'm going to give you more indigestion, a little more pain, in the sense that I want to pick up and push on statements made by Dr. Blumenthal and Paul Egerman. I strongly, strongly encourage the inclusion of privacy incentives in the meaningful use criteria. They're missing, as a category, on your slides, in discussion, and in content.

The stimulus bill was herald by many in the privacy community as, I think some have called it the best privacy bill ever. While I may not necessarily use that characterization, there have been advocates who have. The fact that the meaningful use criteria in the final regs has zero privacy incentives is not good. The idea of letting privacy not be a part of the incentive structure, but somehow be left to a regulatory hammer over somebody's head makes for difficult regulation and loses the beautiful notion of meaningful use as an incentive. I would strongly encourage you to use incentives rather than force to accomplish privacy safeguards. The Privacy and Security Tiger Team are producing the kinds of results that could be operationalized and included. So I would welcome comments on that and certainly hope that you will consider that.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Thank you, Latanya. I think next we have Tony and then David.

Tony Trenkle – CMS – Director of OESS
Just a quick comment back to Judy's earlier statements: One thing that would be helpful, Judy, is not all objectives are created equal in terms of what their impact will be on the change in the systems to meet them, so it would be helpful if we could hear from you what are the key— Okay. Good. I think that would help us a lot in terming things.

David Blumenthal – Department of HHS – National Coordinator for Health IT
David?

David Lansky – Pacific Business Group on Health – President & CEO
Thank you, Paul, for presenting this with the challenges. I want to bring us back to the intension of the program and the three stages that were prescribed in the initial recommendations from ONC. Tell us that we want to get, by stage three, towards a focus on outcomes. I think the more we can keep our eye on that, the less we will get challenged by over-specifying the functional requirements.

We have two pathways, and essentially right now we're working in parallel, our Quality Measures Workgroup and Meaningful Use Workgroup. Meaningful Use has, de facto, been focusing more on the functional requirements and Quality Measures on the measures department, the clinical quality measures. In turn, the clinical quality measures have been beginning to move towards various types of outcome requirements.

I think I don't know how to do this exactly, but I hope we can have a conversation about saying we're going to do what's described here as stepping-stone to stage three and make that a priority that is a first task. From that, work back to whether—to the extent we could have developers work within their clinical systems to achieve the outcomes that are being measured, but not necessarily have ONC or this process specify all the technical requirements that we believe are appropriate to achieving those goals. That'll leave them and the health systems that build out those technologies free to do a variety of things with their platforms that will still achieve meaningful use.

My fear on the other side is if we try to over-specify a long list of functional criteria, we will burden the vendor industry with a lot of rework and uncertainty about the path forward. I hope that's our elegant solution if we can keep our eyes on the outcomes piece of this.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
That is a perfect introduction to the next discussion topic. Judy, did you need to speak?

Judy Faulkner – Epic Systems – Founder
Yes. The one thing I wanted to add, I think the hospitals have to sign up by October, and then with stage ….

David Blumenthal – Department of HHS – National Coordinator for Health IT
They don't have to. They have the option to ….

Judy Faulkner – Epic Systems – Founder
They have the option. With stage one, they only had to be a meaningful user for 90 days within the year, so most of them push it to the end. For stage two, you have to be a meaningful user for the whole year, so there is this very short window, 90 days from the final rule to it has to be in. I want to move it, the discussion, a little bit from it's going to be hard on the vendors. It's going to be hard on the healthcare organizations too. It may endanger patient safety because if the vendors are moving too fast and if the healthcare organizations are putting it in too quickly, it's not just they won't meet the criteria. It's a patient safety issue in the end.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Yes.

Marc Probst – Intermountain Healthcare – CIO
Just really quickly because Latanya wanted to give me a little more angst. On privacy, the law itself imposes huge penalties relative to privacy. I just want to be careful that we don't pile on with incentives more that have to be done that make those incentives or that penalty even more difficult for us to, I guess, not obtain, but never hit. We do have to go back to the root of the law itself and what it does around privacy and be careful that we don't do too much on the incentives side that makes it even more difficult.

Latanya Sweeney – Laboratory for International Data Privacy – Director
Let me just clarify.

Marc Probst – Intermountain Healthcare – CIO
Don't do that.

Latanya Sweeney – Laboratory for International Data Privacy – Director
The penalties are HIPAA, and doing nothing means to say that HIPAA is sufficient. HITECH explicitly says it's not sufficient and begins to raise the bar in many ways.

David Blumenthal – Department of HHS – National Coordinator for Health IT
We'll have a sidebar here, whoever is still standing when you're done. There are two issues here, and they're joined at the hip, but conceptually separate. The first is, ideally, where would we like to be in stage three? Where are we heading? The second is what's the timeframe for getting there? If we bind ourselves to the proposed timeframe in the regulation, we may hold back in our ambitions simply by saying, "Well, I'd love to get to point X, but I can't imagine getting there in 2015." So let's not say we're going to get to point X. Let's say we're going to get to point P because point P is doable in that timeframe.

The other way of approaching it would be to say, we need to get to point X. Let's specify a route, and then attach a timeframe to it. Now those are two separate ways of thinking, and we have a timeframe that we've enunciated in the regulation that remains our timeframe. But I guess I would just encourage us not to curtail our ideals, our vision, simply because we're anxious about the timeframe because, if we do, we will miss an opportunity to conceptualize a very important set of possibilities.

I think the whole question of how you would specify an outcome related incentive is a very interesting one that deserves some thought. I think that the other question, if we spend some time on it, and we might not if we pull in our ambitions over technical, important technical issues, timing issues, we might not confront, for example, how to align our outcome aspirations with those in other areas of the department, what CMS is doing, what the department is doing under the Accountable Care Act authorities. I think we have to give some thought to those issues, at least at a high level because we can't ignore the fact that we are part of a much larger enterprise.

It may be worth having some discussions that aren't tied quite so tightly to the enunciated timeframe, don't commit us, but kind of are aspirational. Then if we need to back off from those, in light of timing realities, we can do so.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
That's very helpful guidance. Just let me ask a clarification point. Is there some flexibility, or would it require new action to change the 2015 timeline?

David Blumenthal – Department of HHS – National Coordinator for Health IT
You're free to recommend to us anything you like, but we've written a regulation, and we're not about to change it on the fly at this moment.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
As a takeaway point, the discussion has gone beyond the question that's before you on the slide, but as a takeaway point from this particular question on the slide, I think you're all endorsing shooting for a stage three kind of objective and criteria, and then finding an incremental path on the way there and calling that stage two. That is mixing both of them, and I didn't mean that they were mutually exclusive, so if people seem to feel comfortable with that. In addition, you've raised a lot of discussion about the time, the timeline, and then we've got some very helpful guidance from Dr. Blumenthal in terms of let's not back off from what we need to do. Even if it doesn't quite fit, at least in this moment in time, the 2015 milepost, and we'll work on that later.

Now teeing up the next point, which is actually maybe the way out of this timeline box, is to focus on outcomes. As you know, even in the statute, it talks about this program is for improving outcomes, not about the software installation. Taking that under advisement, should we, and that was the original intent by the blue matrix, in stage three, really look towards outcomes based measures. The discussion after this particular session is going to focus on the quality measures that are outcomes oriented.

If you looked at stage three as being mostly or at least with a heavy emphasis on outcomes based measures, then at that point would we be setting performance thresholds on what the department feels are high priority areas for the nation's health. Would you be measuring? The advantage of setting those performance thresholds, that is, there may be some kind of floor that says you need to achieve this kind of performance to get your meaningful use incentive dollars. Some of the advantages of that is that we would have a direct tie between what HIT does to enable healthcare organizations to produce better outcomes and the implementation of HIT.

You could also imagine if we have these performance thresholds that you could say you would be deemed in satisfaction of the meaningful use objectives by virtue of the fact that you accomplish this. Your organization accomplished these outcomes and places less of a dependence on this whole process. Less of a dependence on you must have this function certified in this way and a report produced by pushing this button. That actually may be the out that gets us away from the timing problem that we discussed just earlier and the need to be so precise in our specification because really the industry asked for that, and then turn around and say, well, then we have to re-implement what we currently have. Even though it performs the function in spirit, it must perform the function to the letter.

It also, of course, would support value based purchasing. So if in the notion of you're paying for outcomes rather than for transactions, and get the meaningful use incentives aligned with that approach, then we'd have some confidence between this, the value based purchasing, and in ACOs. There'd be a lot of alignment if we went in this direction. The corollary then is we'd put less emphasis on the how and the functions and the specifications and what has to be done in REV 3.5 for a particular vendor's product, and reward much more and essentially deem that you actually must have used HIT because some of these things you can't accomplish without HIT. That's the underlying assumption for the legislation itself.

That would be pretty attractive, and if we went towards stage three as being outcomes based measures, then how will we start introducing that in stage two? Going with our previous conclusion that, let's work on what stage three might look like, and then back into it with stage two. So I introduce these examples, and I called them merely examples so that we don't focus on these and shoot down any one of these examples. But as an example, we all know that we're basically a lot of the meat of the values of using HIT systems is because they provide support for clinical decisions. Whether that's for the professional healthcare team or the patient, it's the clinical decision support.

Instead of enumerating, you've got to use one of this type of decision support, which might be drug interactions, and one of the alert functions, and one of the health maintenance. Instead of enumerating what you must do, why don't we say what you must accomplish? But in the process of saying what you must accomplish, we should say here are different kinds of decision support. Drug interaction is one. Alerts are another type. Reminders are a third, other ways of what I might call coloring choices. In other words, the best way is to make the right thing to do the easiest to do in your software system.

There are lots of ways to influence the choices that providers may take advantage of when they use these systems. But enumerating the kinds of decision support that can be built into these systems, that can turn into certification criteria. We would enumerate the kinds of decision support functionality, hand it to the HIT Standards Committee. They turn it into certification criteria, and that means that the vendor systems that we use, and the self-developed systems that we use, would have the capabilities of the following kinds of decision support functions. It doesn't prescribe what you must use in your organization. In a sense, it's sort of the best of both worlds. Make sure the HIT systems have this capability, but leave it to the provider organizations to take advantage of it in order to accomplish better outcomes.

Another example, merely an example, is the 30-day readmission rate, which so much depends on care coordination functionality in these systems. We know from our hearing that this is probably one of the weakest parts of current systems. They really do not support coordination of care across setting and across different kinds of providers. That's one really positive effect of this kind of incentive program in causing the system to cause us to raise the tide for all of the systems.

The benefit to both patients and society is by reducing the readmission rate. If the department set some goal, let's say, reduce the readmission rate by 10%, just as merely an example, then you could see how it's almost going to depend on the capabilities of the HIT systems. I'll pause here. The notion is, instead of relying on being so precise and so prescriptive on functions in the system, which we never wanted to be in the business of, but had to start somewhere were stage one. Looking towards stage three, is it going to be more rewarding, the using organizations, the provider organizations for accomplishing better outcomes, and how do we back into that? I'm sure there's going to be a rich discussion at this point, but it may be the thing that saves us from the points that were raised in the first discussion.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Just as a point of information, the beacon community program operates on precisely that theory. It specifies outcome goals for the communities, not IT goals on the assumption that IT will have to be used to accomplish the outcome goals.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
The advantage of this program though is when we say that, we can back it up because we're going to require, through certification criteria, that the systems are capable to do that. You already chose people who have HIT systems in the beacon community.

David Blumenthal – Department of HHS – National Coordinator for Health IT
We don't know if they're capable, but we'll find out.

David Bates – Brigham and Women's Hospital – Chief, Div. Internal Medicine

I had the opportunity to present what the plan is on numerous occasions, and I have to say that one of the things that makes me most nervous about our whole plan is the notion that we will be getting to outcomes by 2015 because I think that's very challenging. There are few reasons for this. We don't have measurable outcomes for most conditions or domains. As everybody knows, many outcomes take a long time to develop. The U.K., which has had a quality and outcomes framework for some time now, actually includes almost nothing about outcomes. They have a very established, very elaborate framework that only includes a very little bit about that, and it's not because they haven't wanted to add outcomes measures. It's because they have not been able to define things that they felt it was reasonable to focus on, and that's true. Even though they're paying 40% of primary care salaries based on that.

Now it's quite clear that process and outcomes in many areas are closely linked, and we have good evidence about that. What I think we should be doing is paying for processes associated with outcomes. Then outcomes, when possible, in a few instances, and there are some instances when I think we can do that, but I think it would be risky to put all our eggs in the outcome basket, even though I'm very sympathetic with the desire of some people like the payers to do so.

Judy Faulkner – Epic Systems – Founder
I think outcomes are interesting, and I think, in combination with the others, would be real good. Just a few thoughts: One is, I think we have to be very careful on the testing because if in fact the outcome is general, as you have here, but by the time it gets to the testing rules very specific, we're going to be into some of that same problem we had before that I think we're trying to avoid.

Secondly, I would recommend that if we do outcomes, we recognize that some organizations are already at the top of the game. So it would be hard on them to have an X percent increase because they have already gotten it way up there. Other organizations might not be able to meet an absolute because maybe they're dealing with the indigent population, or maybe they're the heaviest weight state of body mass index in the country, and they're going to have a harder time changing the way their population lives. I would recommend that if you do it, you have both ways. You either attain a certain measure or increase so that you take both those into consideration.

Gayle Harrell – Florida – Former State Legislator
I apologize for being late. I missed the whole discussion on timeframes. I'm sorry I was not here for that because I do want to put my little two cents into it. I have said again and again that I feel our timeframes have been extremely aggressive, and it makes, in the long run, especially as we move into outcomes, if we don't really know the direction we're going in, who sets those outcomes, we are certainly setting ourselves up for failure in that many people who should be able to qualify to meet meaningful use will inadvertently not be able to do so.

I think Judy brought out two very specific points that I was going to make is that people are at different stages getting into the ballgame to start with, with their general population, no less with their ability and sophistication in IT. So you've got different levels.

When you go to outcomes, and this perhaps is a discussion that we'll have over the measures, the Quality Measures Workgroup needs to really address. But you come down to the question of who sets those outcomes. Do we have a general consensus across the board as to what those outcomes should be? You have very specific groups working on measures, on outcomes in each specialty area.

Are we going to allow the committee to go into those areas and say, okay, the College of Cardiology is going to set specific outcomes in cardiology. Is ACOG going to set GYN outcomes? Who is going to set those outcomes? I don't think this committee has the expertise to do that. I don't know that perhaps the ONC has the expertise to do that.

There are many professional groups who are in that business, so I really question that direction in tying meaningful use. Yes, we want to improve outcomes, but you have to be very careful how you set those

parameters and how you set those rules, as we move forward. Just a word of caution, as we move forward into stage three.

Neil Calman – Institute for Family Health – President & Cofounder

I guess one of the things I'm worried about is the sustainability of the change that we're driving. I think we have this sort of short timetable for getting people to qualify for meaningful use. But what we're really trying to do is transform a delivery system over a very long period of time. The capabilities of the systems, to me, and the way they're used is sustainable change, right? The next group of doctors that come in have these things, have the decision support. They're built in. We don't have to recreate this.

I think if you focus on outcomes, and we get too far away from that piece, what happens is we're going to have the experience that people have in quality improvement in general. You focus on something. Things get better. You focus on something else. They get worse again.

Where does the sustainability come in the model? For me, it comes in building the systems, the decision support, the reports, the kind of functionalities in the system that become just part of the tools that we have every day. As people move into those systems, those things drive them to become better providers and to deliver better care without having to go through all of the process stuff that sort of we're going through. I wouldn't want to back down too much from kind of calling out the real capabilities of the systems because I think that's the sustainable piece.

The second thing is I think we have to think about these deltas. Your last example was sort of a delta measure. It's kind of like reduce it by 10% kind of measure. In order to do delta measures without having people do some manual process of have some historical information in something, you have to put the system in and do nothing to improve for a while, so you can at least see how it's functioning and get a baseline measure. I'm really not all that crazy about that idea.

I would love people to be able to put the systems in and use them for improvement, or even start improving now. You start calling out measures that say we're going to pay based upon or qualify you based upon improvement. You actually could stall some people starting on some improvement processes now.

The third thing I wanted to say is kind of a big picture question, which is, I really do believe we all have a limited amount of time and energy to put into meeting meaningful use criteria. I continue to worry about the extent to which, as we call out specific areas for people to work in, we keep them from dealing with local problems that they identify in their organizations, local quality issues that they have to focus their staff time and attention on. We have three projects going on that have nothing to do and aren't even part of these pieces, but they're the three most important projects right now, as identified by our providers and by the specialists who we refer to as being potential quality issues in our own organization. To the extent that we're starting to meet criteria that are set externally, I think we do move away from that. I've heard that from hospital folks as well.

We don't all have the same problems going into this. We've got to leave room for people to focus on specific issues that they identify in their own organizations. Otherwise I do think we're going to end up in a place where we could temporarily sort of lock people up in sort of meeting qualifications and criteria and keep them from doing the kind of improvement projects that they need to do using IT within their own systems. So I would love for use to figure out a way to call that out somehow for people to be able to report on improvement activities that they're using that build on their IT systems, but aren't necessarily the diseases or entities or measures that we think are critical overall. Not to the exclusion of those, but I guess to be very parsimonious in those measures, and yet to be able to call out the fact that we're interested in people using IT to solve sort of local problems.

Marc Probst – Intermountain Healthcare – CIO

I'm under the belief that people get involved in technology and purchase it because they want to get value for their organization and do things more efficiently, and so I am very much in favor of defining the what versus the how to get there. I am intrigued by the outcomes. I think, as Neil suggests, you've got to be very careful on what those measures are, and one that they build on top of what we've already requested people to do. But I think if the right group got together with the right external.

I agree with Gayle. We probably don't have the expertise around this table. You could come up with some very good outcomes or what's, and not be so prescriptive on how to get there. I think we could have a lot of success that way, so I like that thinking.

Paul Egerman – Software Entrepreneur
This is an interesting discussion. It's certainly a physician's view of an IT system where you want to say, "What is it really supposed to do? What's it supposed to accomplish as opposed to all the details?"

I look at this issue though about what should it do versus what should it accomplish in terms of outcomes, and a bit concerned about establishing any kind of thresholds about what those outcomes should be. I'm on the board of a safety net hospital. I just know that whatever outcome threshold you set, we're going to respond by saying our patients are sicker. That's what everybody is going to say if they can't meet whatever the threshold is for whatever reason.

But there perhaps another way I was going to suggest to accomplish this same thing because it's also interesting what you said about supporting value based purchasing. Another way to address this issue would be simply to establish some outcomes measures and, as part of stage three, have transparency, that people have to publish their outcomes measures. Instead of setting particular limits, it would just be the impact of publishing them is by itself an incentive for improvement.

Healthcare is ultimately more competitive that people want to realize. Mass General and the Brigham will compete against each other, even though they're the same organization. They'll actually compete against each other in terms of these kinds of things, so simply publishing them without setting a criteria would add a level of transparency that's actually completely absent in healthcare right now, completely absent.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Can I ask you a question on that though because that's one of the things we've thought about? But then how would you use that to qualify for the HIT incentive? Because then by publishing a rate of zero, you can get, so that's a quandary.

Neil Calman – Institute for Family Health – President & Cofounder
You have to … publish zero. Publishing zero means perhaps that you don't have the data. In other words, you could set the criteria that says you have to have a certain number of patients, a certain number of something.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
No, I meant you actually accomplished zero percent of your hypertensive patients are actually controlled, and should you get money for that?

Neil Calman – Institute for Family Health – President & Cofounder
That's a good question. I suppose there ought to be some response that you have to do something.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
It's called a threshold.

Neil Calman – Institute for Family Health – President & Cofounder
Right.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Maybe, maybe not. Judy?

Judy Faulkner – Epic Systems – Founder
I'm just getting some messages from another EHR vendor, which is very interesting, and one is concerned about the timing and supporting that. There was also a message about maybe this group can go quicker instead of changing the dates for the rest. Maybe we put an earlier timetable on ours.

But the other was a really interesting comment about some announcements of EHR Lite that are coming out that are going to allow you basically to check the boxes. Therefore, I think that makes some sense, so that might be a repercussion. The suggestion was to make sure that we are somehow addressing that we're really trying to get a broad, robust, electronic medical record with broad, robust capabilities rather than a check the box answer.

David Blumenthal – Department of HHS – National Coordinator for Health IT
George, did you want to say something?

George Hripcsak – Dept. of Biomedical Informatics Columbia University – Chair
Yes. I just wanted to point out, we are looking out for those kinds of side effects on the outcome measures negating system, and actually on the structural measures negating the system. We had a long discussion last year about documentation and can people do a Lite system that has no MD documentation, but check enough boxes to get their incentive?

Just to be concrete for a second, what does this workgroup need to do over the next one to three months, given that we don't know the outcome of the outcomes group, and we don't know adoption yet. I think what we need to do is be broad and see what's possible that we need so that we're poised to make decisions three months from now. I think that stage three, from this discussion, stage three for us could be a dialing up of all the thresholds, and stage two is halfway there, higher. Or stage three could be dialing down on the structural measures because we replaced them with outcomes measures, and stage two is halfway there, dialing everything down, in affect. So it's hard to know today what we can do.

What we need to do is just be prepared and think about what are the possibilities, I think, of where we could go and perhaps start thinking now, early for Judy, what are the new structural requirements that we need to put in that we think will really advance the nation that we don't think would be addressed with outcome measures, and start thinking about those early. So maybe patient engagement would be one of the ones that might be harder. I can think of outcomes measures for patient engagement, but maybe that's one that has to be structural.

Neil was talking about sustainability. What will sustain this effort in the long run is the public demanding it. If patient engagement accomplishes that, that will really be the biggest sustainer. I think getting data in the hands of patients may be the thing. I'm not deciding that. I'm just suggesting that would be an example of a discussion we could have of structural measures that would be important to talk about that now, not deciding until later on when we have more data what to actually do.

Neil Calman – Institute for Family Health – President & Cofounder
As you're thinking about those sorts of functional specification things, so here's an example of something. Registry functionality within EHRs, we haven't really called that out yet as something that's a requirement. But yet, a lot of the things that we're sort of dealing with in relationship to outcomes would clearly be supported by that kind of functionality. If you just say, well, let's achieve this certain outcome with diabetes, you haven't really developed that kind of specificity, and you have a lot of EHRs that are being put out there without really good registry functionality. Or do you say we really think we need to call that out specifically as a functionality because it supports so many kinds of projects and things that people are going to do around all different kinds of disease entities going forward, and it enables people to locally sort of focus on problems that they have using a particular type of capability of a system.

That's just one example, but there are other examples of things that we kind of know that the systems need to have, but they're not really, if you get to outcomes without really specifying some of this stuff, I think you have the vendors backing away from some of that kind of functionality, and that's where I agree with you, Paul. At the same time we do this, we have to say exactly what some of these functional requirements have to be, even though they might not have to be used for a particular outcome. But we still have to make sure that we call out what those requirements are, and we have to make sure that we have a place to have a conversation about those, even if they're not really on this list of outcomes.

M
I think that's a good example, Neil, and it's actually apply clinical decision support to achieve outcomes and attempt to do that. So a registry might be in the suite of tools that are in clinical decision support that we want to signal to the certification group. They should be certifying that an EHR can do this, but even our structural measure doesn't say you have to use the registry. The structural measure may be something like what's written up there, or the outcomes measure is the outcome that you're looking for. They can't really be measured without a registry, but it's mainly us being able to get it over to the certification group, so the sweet of tools that we want people to choose from can be done. Now whether it's flexible, and you can do two out of three, two out of six clinical decision support tools so that Judy can actually get that thing done is something that the certification group would have to look at.

Gayle Harrell – Florida – Former State Legislator
Certainly I think one of the things that is absolutely imperative that you look at in stage two and something that really sets up for outcome measures and making sure the care coordination is certainly the most important is one of the most important elements. Care coordination, especially across settings, requires interoperability. I think dialing up the interoperability in stage two is absolutely essential. In order to move to stage three, you've got to have that interoperability, and that, I think, has to be built in within systems. Then we also need to look at that information exchange and where we're going with our HIOs and HIEs. So that all to me is the most critical component in moving towards stage three that needs to happen in stage two.

M
How should we organize that given the number of workgroups that we have under this committee? What is the best way? We don't want to go off and do it ourselves in effective, right, because we have experts on other workgroups and tiger teams, so we'll need to work on how to organize that.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Yes.

Paul Egerman – Software Entrepreneur
I just wanted to pick up on the comment you made, George, about certification and tools, and make a suggestion that one way to address these timing concerns would be to decouple the certification process from the meaningful use process. By that I mean, you view the EHR as a series of tools. You could set a deadline, say April 1st, and say that's when you're going to complete stage two, the final rule for stage two certification.

You could then do some of your meaningful use things a little bit later with the understanding that you're sort of like constrained by whatever was in that toolbox in stage two. But that means you could set deployment levels differently, and so that would also be consistent with what previous comments were about focusing on interoperability or information exchange or privacy and security. But that would be one way of doing it. Set a date, April 1st. You get the toolbox done. View it as a toolbox. Then you can go ahead and focus on determining what are the deployment levels that are going to be required to succeed.

David Blumenthal – Department of HHS – National Coordinator for Health IT

Can I just make a couple of comments? It's been a terrific discussion. For all of us who have been through the wars on quality measurement, I look at David Lansky. I look at David Bates. There are others around the table who have been there as well. We all have been through these discussions about threshold versus deltas. Do you reward a level of accomplishment as opposed to a trend in accomplishment or both? What do you do with variation at baseline? How do you acknowledge that people start at different places? Also, how do you do risk adjustments?

Those are all issues that are inherent in the quality discussion. They're being thrashed out in other parts of the department as we speak. We have to have, by January, on the ACA statute, the department has to have a national quality strategy by January 1st.

With regard to the expertise on this committee, we are not alone. We can depend on work that's going to be done elsewhere in the department for guidance on what quality measures we might want to incorporate. For example, if we were going to use outcome measures, we wouldn't want to create them ourselves. We'd want to make sure that they were coordinated with outcome measures that were embraced by the department, that were part of the ACO framework, if they were part of that, and that we were consistent with and reinforcing national policy on outcome improvement.

Just hypothetically, if the department were to say our number one priority is to reduce death from myocardial infarction and stroke, that would be elevate hypertension control as a goal. It might cause us to say that the number one outcome that we're going to measure and the structural criterion we're going to look for is a registry of hypertensives and improved blood pressure control as a meaningful use of the registry. I think that as we focus on outcomes, we will have to, to some degree, step back and say we are committed in principle to outcomes, but we can't specify unilaterally which outcomes we're going to elevate to the key outcomes we're going to focus on. That's going to depend in part on work that's being done elsewhere, and we will stay flexible and adjust.

But in the meantime, for stage two, knowing that maybe this will be clarified well within the framework of our rulemaking for the second stage of meaningful use. If it weren't, then we would have to say outcomes and process and structure are not either/or. They're yes/and issues. We'll pick the structural measures and the process measures that we think are highly likely to yield outcome improvement based on the best literature and the best science that we know.

So I think though that there is value in thinking about where we want to end up based on the old Yogi Bear truism that if you don't know where you're going, you're not likely to get there, and so it won't be sufficient to specify outcomes. For one thing, outcomes don't focus you enough necessarily on privacy and security issues. They have a different sort of outcome is the focus on privacy and security. It's an outcome related to trust and the public support of the work we're doing. So we need to keep that in mind as well.

There is, I think, a general sense that if we were to keep adding on to the approach we took in stage one, which is to keep adding functionalities and requirements around functionalities, that that would lead to a proliferation of specific metrics that would be in danger of collapsing of its own weight. Would lose credibility in the community because it would look like we were micromanaging Neil's community health centers and Marc's hospitals and clinics. There is a kind of liberating quality to stepping back and saying just do good. Use HIT. Do good. We'll reward you for doing good.

M
HT … good.

M
(Inaudible.)

David Blumenthal – Department of HHS – National Coordinator for Health IT

Obviously I've provoked some thoughts from Christine, so do you want to jump in?

Christine Bechtel – National Partnership for Women & Families – VP
I've been listening to the discussion and I definitely get the tension over outcomes versus features and functions. It's been a long running discussion we've had since the beginning and probably since the beginning of time going back to all the quality measure work in the broader world.

But one of the things that is striking to me is the role of patients in figuring out what we ought to do here in terms of outcomes and features and functions. As I am absorbing everybody's comments around these two approaches, one of the things that occurs to me is the role of the patient experience survey, whether that is something that we already know like CAPS or it's an adaptation, it's notable that these surveys ask patients, how well is your doctor doing at care coordination? Are your health outcomes improving? Are you engaged into your decision-making? Is your provider using health IT? Do they do secure messaging? Do they have a portal or a Website? All of these are tested and validated questions.

I don't think it gets us all the way there. But I think, if we're looking at parsimony, and we're looking to try to balance these approaches, and we're looking to try to create capacity in the system, as Neil talked about, for the system to be able to focus on overall health outcomes improvement regardless of topic, whether it's a local priority or a national priority, it just seems to me that this certainly ought to be a very large piece of the puzzle that we look closely at because it can be HIT enabled, although it is not the same construct as something like blood pressure control where you need the clinical data from health IT. It is a different kind of HIT enablement, and I get that. But I think that's okay if what Congress asked us to do was to measure and look at improving overall clinical outcomes. Certainly patient experience assessments are a huge tool that could enable use to do that.

Then the other thing I want to say is something I have said before. As I think about stage two and what has been set forth, I think by ONC around sort of the focus of each stage, stage two being information exchange, I think we really need to understand where NHIN Direct is, where it's going, when it's going to get there, and all of those things because I think the world of interoperability has been a challenge for some time, and that had some really nice promise early. So I think it would be helpful at some point to know how that work might play into meaningful use and how scaleable it is.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Should we move on?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
I think so. We've got to watch our time because the issues aren't getting any easier. The reason we put this before you is because there is diversity of opinion, and we don't have a preponderance of one side or the other, and maybe it's comforting to see that the discussion reflects that diversity of opinion. That reminds me of Yogi Berra's other comment, which is, "When you see a fork in the road, take it." I think that's the advice you've given back to us.

Christine teed up the third area we'd like to get your input on, and so patients having access or consumers having access to their data is fairly new. You would love to have them have the market give them innovative ways of making good use of that data. In the final rule, and part of our draft as well, there are concepts and words that had caused some confusion that we'd like to see if there's a way to consolidate them around things that concepts, basic concepts that are more understandable and get us to where we want to go. Words that appear in the rule include access, copy, clinical summaries, discharge instructions, and we're trying to see what are the true distinctions that are trying to be made, and is there a way to simplify that.

As we tried to break it up, we actually did try to almost consolidate them into one construct, but that turned out to be fairly hard because immediately, ambulatory care and hospital care are fairly different.

Ambulatory is this ongoing process that you periodically check, and hospital is this major acute event. Are the things that you do with the information that similar? Probably not, is one of the guesses we have.

Now the other is to try to nail down, what do we mean by access versus copy and download in some of these specific use documents? Here's a construct that may help, and see if that helps for you. Access may be the actual goal that we have. If everybody had access to their record, then at any time they could not only download it, but copy it, print it, and share it and whatever. So when that state becomes available, we may solve a lot of the patient's ability to use their data in other ways.

That may then replace the whole notion of copy in the future. Copy right now is analogous to the paper record setting where you walk up to the HIM department and say, I'd like a copy at this point in time of all my information. That's sort of a point in time access. You get this information. The rule would say that you'd get it in electronic format. Another way of saying it is you can download it. That may be hopefully just an interim step between where we are now and when we all can have just access to the shared record that our providers have.

Then there are specific use documents. For example, in the hospital, as you make your transition from in the inpatient setting to home or wherever you're going, there's a communication that currently we fall short on giving patients enough information to the next step. That's probably part of the reason we have this high readmission rate. We want to be able to make these discharge instructions to be available at the time you're leaving the hospital.

Similarly, in the ambulatory care world, there are these clinical summaries. That's how it's called out of the rule. Ways that you can leave the office, get through the inquisition from your significant other at home, and help transfer the information to the next person that may see you, whether that's a specialist or whatever the next person that's involved in your health. I think that is one way of looking at this, and maybe you can help us think about the whole notion of how do we give people. What's a desirable state in giving patients access to their information, so they can make other uses of it in support of their health?

David Blumenthal – Department of HHS – National Coordinator for Health IT
Paul, just as a time check, you have one other major topic? This is an incredibly rich, broad topic that we'll, I'm sure, occasion a lot of discussion. But we won't have time to do it in the detail we'd like, so let's spend ten minutes on this, and knowing that we don't have to resolve it today, we can come back to it. Then we'll go on to the next issue, so we can finish in time.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Right. Thank you.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Yes, Latanya.

Latanya Sweeney – Laboratory for International Data Privacy – Director
Clearly the specific use documents are really important. Accessing copy … the copy doesn't necessarily have the specific meaning that you said. It doesn't necessarily go away. If you want to empower patients, they need both access and copy because copy allows them the ability to move the data. It allows them to do things with it, so having an electronic copy— For example, if a person is across 20 different providers, the care has been coordinated across 20, and there are 20 different portals to access, then in some sense it's not helping. And then if they move out to another state, then there are more portals. Then they become the management of these portals. Each portal may have its own way of operating, operating over different systems, so you haven't helped them in a sense. You haven't really empowered them as much. But if in fact they could actually acquire so that electronic versions could move to some other repository, then in fact they have another kind of option.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

That's fair. Probably Christine is going to clarify.

Christine Bechtel – National Partnership for Women & Families – VP
Yes. This is the fundamental flaw in this construct is that at least in, and other workgroup members can correct me if they think I'm wrong, which is, at least in the original construct, we meant for access to be portable. We meant for it to be that real time. In fact Paul said it in his remarks, although it's not reflected in the slide. It's access to real time, portable information. We were thinking originally of copy in the HIPAA construct. If you get a copy of your paper chart, and that could be on USB stick, or it could be a PDF that's e-mailed to you or whatever. That's the challenge that we're trying to address. We definitely want to see the portability.

We've looked at the models that the VA and Medicare are putting forward or about to put forward around the blue button concept. I think that's a key distinction that we have to make, and we've just really struggled and are absolutely not done yet to figure out how to combine these in a different construct that is still a glide path for providers. Yet, at the same time, actually allows a lot more mobility of information for consumers because I had the same concern you do, Latanya, that I'm going to have seven different portals and no way to combine my information.

Latanya Sweeney – Laboratory for International Data Privacy – Director
Yes, and I think those words have really loaded meaning if you'd survey the scene right now and how people are interpreting things. So access and copy, access definitely doesn't have an idea of portability or the scope of the data.

Christine Bechtel – National Partnership for Women & Families – VP
So I think, to the extent you might be willing to help us think through new terminology, I think that would be good because I think this is a matter where we've tried to— I worry that we get stuck in the glide path notion because we want to build on things. But I think we're building on the wrong blocks. I think we need to not be afraid to say, okay, we need to scrap that just out of clarification's sake, and this is what we mean, and it still builds on the concept.

For example, clinical summary, it lists an enormous set of data elements, much more specifically than discharge instructions or than access or than copy. How do we take that as a building block and really build that and then add the portability pieces in? You're thinking and input would be very welcome.

David Blumenthal – Department of HHS – National Coordinator for Health IT
David Lansky?

David Lansky – Pacific Business Group on Health – President & CEO
What this raises for me, going back to Neil's comment about registries. In general, I don't think we've done enough work. We've dabbled in it about essentially the longitudinal record, whether it's professionally serviced or patient serviced? I'm wondering whether, and keeping with Christine's comments, we've got three interoperability platforms. We've got HIEs. We have registries. We have the blue button PHR repository model. We're leaving them all loose in the ecosystem right now. The inputs to them are imprecisely specified, and the outputs and uses from them are wide open, which maybe is good.

We all believe that there's an opportunity for new applications or apps in the personal space to be sitting on top of these aggregations of data. We want to cultivate that. Part of what that takes me to is we've got to really reinforce the idea that every EHR that we're talking about here is just a node in the network. It's not in itself a full featured anything, and it doesn't even have access to all the data that would be needed for a full featured anything.

But somehow, I think, in this domain, we've got to get away from sort of the cross-sectional snapshot of data paradigm, except in the sense if it's a feeder into a larger data ecosystem, which these new

applications, whether clinical decision support or iPhone apps, are going to be sitting on top of. So I guess I'm hoping, in a sense, we don't bog down in this debate on this last point about access, copy, download, but we sort of liberate ourselves into thinking of the data as more liquid and fluid and in service of other applications, which are where the value and meaningfulness come from.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Gayle?

Gayle Harrell – Florida – Former State Legislator
I think this is absolutely the best example of the need for PHRs, whether it's blue button or whatever you want to call it. I think this is where you can really empower patients, and you get into that interoperability issue and certification of EHRs in such a way so that personal health records can download that information right into your own PHR. Then you have that. You have your own personal record that you have all those 7 portals or 20 portals all being able to take your information and coordinate it so that you get that same snapshot. You get that same view that your physician will get when he has all those records integrated into your record.

I think that the discussion needs to go a little broader here and go into the PHR. I don't know what ability ONC has to be of influence and where that marketplace goes, or some direction that can be given to some degree. But I think there's a real opportunity for patients in this arena to have all the information they need through that PHR.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Marc?

Marc Probst – Intermountain Healthcare – CIO
Yes, just real quickly, and really, David, that was very well said, David Lansky. The one concern I would have is that we could get this out of scope so fast that we could never accomplish it. I think, directionally, what David Lansky said is right on that fluidity today that the data to be used in whatever kind of application, and to the extent we can get standards and things out there to help support that. But I'm a little concerned in the four years that are remaining how far we can go. I really support the access concept. Well, I like the way you've outlined it. I agree we shouldn't put ourselves in a box, but we need to be careful we don't let the scope get out of control.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Neil?

Neil Calman – Institute for Family Health – President & Cofounder
I guess it was last week, but it could have been last month. I think it was last week that some of us were in a meeting at Markle, and we saw an example of the blue button functionality of the VA system, which basically just put out a text file. An experiment sort of that was done with asking different vendors to build functionality on top of that.

I was just so impressed, I mean, by the kind of applications that people could build around that with very little sort of specification. I think what we need to do in this space, what I would think is to go back and really call out that we need a specification for how this download thing should work so that people can start building applications. That, to speak to Gayle's point, what you really want to do is you really want to get wherever people go to be able to put out the record, whether it's a hospital record or a provider record into some framework so that people will build apps that will enable the users, the patients, the people in this country to take that information. They can pick a way they want to view it.

We saw an app that focused on radiology stuff. We saw an app that focused on sort of creating like a dashboard for people to use. I think that's really what we want. We want people to have different ways of viewing their record. I don't think any vendor is going to come up with 12 different views of their record.

So let's specify how this data should be output, and I think that will call out sort of the private marketplace to do really incredible things in order to help people engage with that information.

David Blumenthal – Department of HHS – National Coordinator for Health IT
So we could discuss this a lot more. I think that Christine's question, which is, how do we make sure that we're building on the right foundation, I think, is in some ways the right question. We can't anticipate all the uses that might be put, that this data might be put to, but what we can do is set goals and certification. Set goals that in turn are translated to certification criteria and standards that enable the transfer of information into forms that are usable in many different ways by patients and family members. It seems to me that this is inseparable from the discussion about interoperability. If you want this to be computable information, then it has to be, in a sense, sharable, electronically sharable, which is the equivalent of interoperability or information exchange.

As we build out the information exchange standards and capabilities, the idea that they should be the foundational standards we set should support these uses, and that we should be able to certify records against them. Then we can have the option of setting goals that constitute uses that we think are essential. We could be very modest in those initial goals, as long as we know that we're building them on the right foundation. In a sense, what this group can do is say, we think that this set of goals, maybe not in 2013, maybe it's 2015, but this is where we're heading. We want this to be a capability of the electronic health records that are creating policy for. We can do that. Then the Standards Committee can turn those into standards and certification criteria, and then we will have that for stage two of meaningful use or stage three of meaningful use.

Let's move on to the ….

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
That was very helpful. Thank you. This final discussion point actually does build on this previous conversation, the ecosystems that David Lansky talked about. We want to head towards the same goal, and to the extent that we harmonize the kinds of things we're asking the provider community to do, the better. It speaks to Neil's question of, you know, we all have local priorities. We can't just be shifting off of them in pursuit of some random event.

The goal really is to tie this program to the evolving goals of other programs. ACO is one of those. In theory, in the ideal world, we would be facilitating and actually helping organizations accomplish what they already want to do or need to do. If the world is moving towards ACO-like constructs, it would be wonderful if we helped move the EHR products to support those.

The concept here is to say how can we interact with other requirements or programs in the ecosystem? For example, and again, these are merely examples or hypothetical examples. We already have things like, constructs like a medical home, and that is maybe part of ACOs. But we would like the systems we use, the HIT systems we use to support that. Could we even get two-for's out of it. Could satisfying a meaningful use objective in, let's say, care coordination, which is crucial for either ACOs or medical homes, be deemed as partial satisfaction of accreditation for being a medical home or an ACO? Or could it be the other way around? If there are more precise definitions in either of these other delivery models, could that be partial satisfaction of the meaningful use objective?

Another example is certification of professional competence such as in medical boards where not only you have licensing, but you're board certified, and currently you're not just certified at one point in time. You have to maintain that certification of MOC. Part of the approach to certification is not only to prove that you have book knowledge through exams, but that you actually are improving your own practice. A component of recertification is that you use information about your practice, about your patient population, and use it to improve what you do for them. That sounds a whole lot like what we're trying to do with meaningful use.

Could meaningful use, which shows that you not only have these systems, but you know how to use them to improve the care of your patients, could that be partial satisfaction of some of the requirements of maintenance of certification or the other way around? The whole notion of can we build meaningful use criteria so that it is synergistic and harmonized with other programs that are going on to improve the practice of medicine in this country? Thoughts on that?

David Blumenthal – Department of HHS – National Coordinator for Health IT
Let me generalize the question a little bit. It has to do with whether we are going to— We might, for all or part of our meaningful use criteria, create separate classes of institutions so that some folks would say, I'm going to be a vanilla meaningful user. Then they would have to report to CMS all the criteria that we've established, whatever they happen to be. Another group might say, I think, if I've accomplished, let's say, I've accomplished performance outcomes that are three standard deviations better than my class of institution on ten outcome criteria, and I've done it using HIT, I should be kind of exempted from the task of checking all the boxes because I'm there. I'm where you want me to be, and I've sort of risen above, in a sense, the criteria that you've put in the regulation.

This is what Paul has highlighted here is some very specific ways in which a particular outside organization might deem or the standards applied by a particular outside organization might put an organization in a different class that was deemed a meaningful user. But there could be other criteria. We could outline a separate track. I'm not saying we should, but it's something we could discuss.

So if Intermountain were to come in and say we've got heart attack rates, cancer rates, survival rates that are two standard deviations better than the meaning for comparable institutions, you can come check our IT system. We use IT in everything. Call it the meaningful user. That would be a potential way of getting to meaningful use. Now we haven't run this by our office of general council. We don't know if it's consistent with the intent of the law, all this stuff, but you guys are not bound by what the general council thinks. You're free to advise us however you think, so I think that's where this is going.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Can I ask, is this a little overlap with the second question, which is the outcomes focus and getting deemed for satisfying meaningful use?

David Blumenthal – Department of HHS – National Coordinator for Health IT
Yes. It takes the outcomes focus out of everybody to a kind of a choice. Anyway, yes, sir ….

M
Paul, just for clarification, you use an example of practice, a physician practice. And David used the example of organizations. A couple questions: One is, would a MOC model where you depend on maintenance certification, that's a different kind of data than the other example. It's self-reported data, and it's going to differ by specialty. I don't know what the broad range is by specialty, but I would imagine there's a lot of variability, which creates heterogeneity, which makes it hard. Is it auditable? If you're depending on an organization to give you data from their health IT, presumably somebody will go and audit that information. That's very different than self-report about your practice characteristics.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
To use this model for that specific hypothetical example, you could imagine how you could make it so that the board that you—that it's not self-reported. That the board has something, a … patient that gets downloaded where, in some way, it actually makes use of your EHR in submitting proof that you look at a registry of this kind of patient and improve the control of that particular disease condition. It would go beyond the self-report and actually turn that to be more efficient for the provider, but also a better indicator of how that provider is practicing. It would take it to the next level, but hopefully would do it together with the professional board in that example.

David Blumenthal – Department of HHS – National Coordinator for Health IT

Christine?

Christine Bechtel – National Partnership for Women & Families – VP
I had some thoughts about the concepts and the questions that are on the slide that Paul referred. David, I think you're bringing up another way to look at it, that I don't think my brain has wrapped around yet, so maybe we'll come back to that. But I would say, at least with respect to the slide, I like the idea very much of looking for synergy and integration and giving people less criteria to meet globally than more for sure.

That being said, here's the kicker: I think it's a question that is hard to answer in the abstract because, when I think about ACOs, they don't exist. I don't know what the criteria are. I don't know how well they're going to map. But medical homes do exist, and that takes me to thinking about whose criteria are we assessing again? Is it NCQA's, which clearly is playing a leadership role in the market? But CMS has maybe could add to those in a way that we haven't anticipated, and JCAHO and others and URAC are developing their own.

I think the question isn't which way do the arrows go. I think the question is how we get them going both ways so that if we were to stack up criteria for medical home and say meaningful use, if you're a meaningful user, it gets you 90% of what's in the medical home, let's say, care coordination criteria. But then we have to look the other way. I think Paul's point is right, which is, what is it that meaningful use is missing that the medical home standards have that we need to make sure that systems have the capacity to do in order to achieve, that kind of moving the market.

We heard a lot about that in the care coordination hearing that they're not set up well for certain kinds of team-based coordination. So I think it's both directions, and they need to inform each other. To the extent that we look for synergies, I think we should. But, David, maybe you could say a little bit more about, are you thinking about different tracks of meaningful use that you could build? I'm a meaningful user with a specialization in care coordination, and if I do that, then I'm deemed to meet some components of the other model.

David Blumenthal – Department of HHS – National Coordinator for Health IT
I don't want to impose a construct on the working group, but this is, I think, a micro example of tracking within meaningful use. I'm on the medical home track. I'm on the main certification track. I'm in because they are morally equivalent.

Then you get into the issue of how you define a medical home, and how do you define maintenance and certification? Those are all, of course, things that one would have to work out before you deem somebody home free with those. But it's part of the same generic strategy. Can you get to meaningful use by different groups?

The outcome group is one way to dodge the issue of forcing everyone to testify to outcomes or achieve outcomes is to create an outcome group to meaningful use so that you can do the checklist if you want, or you could do the outcome group. I'm just posing that as something to think about. It's more flexibility, and it's a greater monitoring chore in some sense, but it could also be, maybe if it's correctly constructed, it might not be more complicated. I think Gayle is next.

Gayle Harrell – Florida – Former State Legislator
When I first look at this, I said, do we have the statutory authority to even broach this subject, and I don't know. I think that's number one that needs to be determined whether the statute does allow these kinds of external certification.

To me, that opens a whole new box that really needs to be explored if that is indeed a possibility because, at that point, you can solve if you have external groups, and perhaps you have various specialty societies. And this is perhaps a mechanism whereby we've kind of pigeonholed our whole discussion

about generalist, internist, general practice kinds of, medical home kind of models. But we are missing the boat on so many of our specialties, our ophthalmologists, our dermatologists, our orthopedists, who we want to be part of this whole thing, and we need those records. We need them to be part of it.

If there were a way to decentralize to some degree and allow some of our specialty groups to get into this as well, and determine those criteria for certification to say how am I meaningfully using that electronic health record to improve healthcare in ophthalmology for instance of orthopedics. You can go down a whole different track. It starts really opening a box and thinking yes. This can be a possibility. So I think it's kind of an exciting idea. I'm really thinking that perhaps we ought to look at that further and make sure, number one, you have the statutory authority to go down that path. But, two, go ahead and open that box. See what's inside.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Let's see who's next. Neil?

Neil Calman – Institute for Family Health – President & Cofounder
I like the idea too. I think it's intriguing, but I have a question and then a comment. My question first of all is, would this have to go through the same process that we're going through with our one set of criteria that we're struggling over creating for 2013 and 2015, and now we're going to have like a whole other track of criteria that we're going to try to define, and then a third one? Are we saying that we actually think that we have the capability of developing three alternative sets of criteria for 2013? Tony, are you still alive? I keep looking over to you to see if I need to run over there and resuscitate or anything.

Tony Trenkle – CMS – Director of OESS
I just announced my resignation.

Neil Calman – Institute for Family Health – President & Cofounder
So I do think it's great. If the practicality is anywhere close to real, I think it's definitely worth exploring. Here's a comment. I think that is what real, no matter what we say about what the deeming process is, synergizing these things is so critical. From the provider point of view, just think about the madness that people are going through. They hear ACO, and it's like, oh, my God. It's another.

Then NCQA comes out with their criteria, and people are thinking, so I haven't even gotten to stage one of medical home, and I'm trying to figure out what I'm building on here. It's crazy. Then you have whatever other authorities you're dealing with as well. The thing that's exciting about it though is I think we really do need a way to look at the criteria and figure out what's missing from what we're doing, especially on the specification side that makes it very difficult for people to meet, like medical home with current electronic health records.

Here's a great example. One of the things you have to do in medical home is you have to be able to show that you're receiving records from and reports from all the specialists you send out to. All of us in primary care know that that's a continuing problem. So we get lists of people for whom we've made referrals and haven't received reports, but there's no aggregated way, right, in some of the systems that we've looked at for somebody to just say, hey, send out a letter to all these people saying please send me a report on the people that you've seen. Right? So that's got to be done by somebody else or the actionable list thing, the way of being able to do population management through registries.

All of this stuff are functionalities we need for medical home and will be for ACO. There will be other things as well. I think we do need to look through those criteria and find out where we're missing, potentially missing functionality that needs to be built into systems so that it supports folks doing those things. Whether or not we create a deeming mechanism, I think that's another level on top of that.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Great. Paul?

Paul Egerman – Software Entrepreneur
Thank you. It was a fascinating discussion. I was very interested in what you said, Dr. Blumenthal, when you were talking about the separate tracks and classes. I was sort of like with you every step of the way until you said, as an example, Intermountain Healthcare might be in a separate class, because I thought to myself, well, gee, I do work with Boston Medical Center, and it's not fair if Boston Medical Center has to be in the same class as Intermountain Healthcare. The criteria might not be something that we can meet as the safety net institution. What's important is that if we're establishing separate classes, which is probably what the general council will eventually say that there's no sort of like economic aspects of the classes. That fundamentally that poor institutions are able to participate in the same way, so that's going to be an interesting challenge.

I also had a comment about the word external on this slide, which is basically, it would be my own personal preference is however, whatever we do for classes, or however you qualify for meaningful use, I would like the criteria to be like as clear and as objective as possible so that there's no need for opinion and interpretation. I'd prefer that there wasn't any self attestation. I'd like to see it just be a very clear, bright line. So I hear about external bodies that determine whether or not you qualify for meaningful use. I think, like as a businessman, that's like having an auditor reviewing your financials. I've got to tell you, I've never liked that. It was expensive. It was time-consuming, and I didn't particularly like that. So, if we're going to simplify this and make it more related to results orientation, as opposed to function and features, which is good, there ought to be a way to do that that doesn't require subjectivity or outside experts to determine whether or not you succeeded.

David Blumenthal – Department of HHS – National Coordinator for Health IT
David Lansky?

David Lansky – Pacific Business Group on Health – President & CEO
I completely support the ultimate objective of having the metrics aligned, the criteria aligned, but I'm pretty nervous about this concept of deeming because I think the roles are flipped from where I would rather see them be. The history of these various private bodies, NCQA, MOC, through ABMS and so on, is a struggle to deal with industry interests, which tilt the process one way or another. I think the opportunity and the burden of HITECH is it's a very large federal investment that's meant to spend public dollars on public interest. The criteria determination should be managed through a public and accountable process like we've been laboring under the last year and a half here.

I think then, if that's successful, and there's $20 billion, $30 billion put into the market in support of that program, that should induce other private initiatives, whether medical certification programs or organizational accreditation programs to follow behind the leadership of the federal investment and what was in HITECH and ACA. So I think it would be great if the industry, broadly described, takes up the work that we are doing and incorporates it as a CCHIT and does align with it. Certainly participates in this process to influence what we do, so that we take the benefit of their expertise and activity, but not to have us become dependent upon those private interests to determine what the public interest looks like.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
You're favoring the way it's laid out here, which is, they use our certification.

David Lansky – Pacific Business Group on Health – President & CEO
Right. Yes.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Art?

Art Davidson – Public Health Informatics at Denver Public Health – Director

Yes. I just want to get back to this idea about, first of all, with regard to the lower bullet there complementing rather than supplanting with this deeming process from the boards and specialties seems like a reasonable approach. But I'm in agreement with what was said earlier about the concern that self-reporting is just not the right approach.

With regard to the suggestion about tracking, let's say, for patient centered medical home and an institution being three standard deviations above. I'm concerned that an institution that's achieved that level may have done that because of its local resources and the network that exists, and doesn't necessarily achieve what David Lansky mentioned earlier about this data fluidity. It doesn't promise that.

Our priorities, as we establish at the very beginning, included the areas of population and public health. You may be great at PCMH, but you may not be involved in anything related to the population and public health measures. Those are things that I think you need to assure, if we decided to go with tracking, that you haven't forgotten some of the other priorities we set forth.

David Blumenthal – Department of HHS – National Coordinator for Health IT
All right. It's been, as expected, a very rich discussion. We hadn't come to conclusion on a lot of things, but I don't think that's a problem at this stage. I know that George and Paul would have loved to have us tell them which fork to take. They may still be on the point of the fork at this point. But I think that the conversation has raised some issues that they could take back to make the choices a little more pointed. We can resurface those choices later on. I want to thank them both for their very hard work and their working groups' hard work. Do you want to just go through the timeline?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Yes. Originally, we were going to get some directional guidance from you here. Thank you for the rich discussion. I think it's more likely that we would come back in December, and the only hesitation was December was scheduled to be a possible phone call rather than face-to-face. I think discussions like this should be face-to-face, so that would be the only caveat was, I think it's better timing to give us some more time to incorporate the comments that we've just received and prepare a better product for you in December.

Then we were planning to release it and avoid the holiday time this time around in January for a request for comment. That gives the public another chance to give us more detailed feedback about the proposal that we would put forward at that time. Analyze that. Incorporate the feedback from the stage one meaningful use submissions, and then target summer to get the final recommendations from this group, the HIT Policy Committee, out to ONC and CMS, which would sort of mimic last year's timeline.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Great. Thank you very much, Paul.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Thank you.

George Hripcsak – Dept. of Biomedical Informatics Columbia University – Chair
Thank you.

David Blumenthal – Department of HHS – National Coordinator for Health IT
We don't have a break scheduled this morning. If you need get out and take a break, please do so, but I think we'll continue through to lunch. David Lansky is going to lead the next discussion, and I'm going to cheer him on.

David Lansky – Pacific Business Group on Health – President & CEO
Thank you, David. We're now turning to the second branch of the meaningful use criteria, which are around the quality measures that had been elaborated in stage one, and we're now discussing how they

should be framed for stage two and perhaps stage three. We have created a set of tiger teams to delve into the details underneath the larger concept of clinical quality measures. Before I can take you into the different teams and where we are in the process, I just want to make a few contextual comments about the work we're trying to do as a workgroup.

We have not tried to reassess the quality measures that are already published in stage one, and we have not specifically looked at whether to add to them, revisit them, etc. The current structure and the content of the stage one clinical quality measures are intact. That may be something we need to come back to.

There is a parallel path going on of retooling a number of measures, so they will be suitable for use in the clinical quality measures pool, and so those, you'll recall, the core measures and the menu measures and having different specialty disciplines report some of the measures from the different menu sets. We have not yet really delved into that area. Instead, what we've done is looked at what we're calling the gap areas, which are areas of measurement of clinical quality measurement, which are not adequately addressed by the previously identified clinical quality measures, but which are consistent with the charge to this committee. The expectation of these groups, as much as in our last hour that we will evolve towards outcome measures, but we don't think, as David Bates suggested, we can't do that overnight, and don't know exactly where that goes in each discipline on each domain, so we will talk to you a little bit about that here this morning.

I just wanted to tee up a few issues that I think are contextual for what we're doing that this committee will, at some point in the next six or nine months, probably need to come back to. One is the role of the electronic health record as the data capture platform for clinical quality measures versus other external data sources. So we will talk some even today about patient engagement measures, as Christine said earlier, that could be captured through patient surveys or other platforms that are not part of the EHR. So I think this body has to look back to its charge and decide, is that something we are comfortable talking about and recommending as a way of assessing the progress of HIT. But we look to other sources of data to do that assessment.

That'll come up both in the area of patient engagement and the area of care coordination, whereas, we said earlier, no individual EHR is probably well suited to tell you everything about care coordination. How do we capture data that is outside of the structure of any one platform? As we said in the last hour, that probably implicates both HIE and registries. So again, going outside of where stage one allowed an isolated EHR to be its own reporting platform, that may not work for stages two and three if we do these kinds of clinical quality measures in these domains.

The second issue we'll have to think about is CMS put forward the model of core measures and menu measures with different disciplines picking from the menu. Is that a sustainable framework? Back to David Blumenthal's previous points about the proliferation of specialty measures, do we want to keep going down that road, or do we need to find a new way of thinking about clinical quality measures that are crosscutting.

The third issue is the role of what we're calling leading conditions. Do we want to have batteries of measures for certain health conditions like breast cancer, heart failure, Alzheimer's, whatever they might be? Or do we want to do it by medical discipline or by crosscutting competencies of the health system?

The fourth area we're going to struggle with is consolidating the plurality of measures into an elegant few, and essentially building up the core and reducing the proliferation by specialty. The last one, David Blumenthal talked about this morning, is how do we align with the other efforts: ACOs, the innovation center and what measures they may require out of funded innovations from CMS, pay for performance programs, value based payment modifier. There's a whole array of things that are part of the reform process. I don't think want to be an outlier to that. We want to be part of that. But what is our mechanism for aligning this discussion with those discussions without us getting too far ahead of whatever else is going on in the agency.

What I want to present to you today is the work of about four weeks from a series of tiger teams. They have done really heroic, admirable work, and gone very deep very quickly. You see here a list of five tiger teams that are by topic, by health domain, and then a sixth one that is by methodological area, which that group has not yet met. They're the one at the bottom of the slide.

We talked about this briefly last month. We've got these five areas: care coordination, efficiency, which is a large bucket, including underuse and overuse of resources, patient safety, patient and family engagement, and population and public health. Now these five areas each has a tiger team, which has been meeting a couple times in the last month. I think one task for us today as a Policy Committee is to look at these five categories, and it's in the bold ink here, and say, are these the right five areas for us to flush out clinical quality measurement in? Knowing that there's also the large array of clinical process measures, which are already in play in stage one and will be expanded probably for stage two. We're going to look at each of these five areas in more detail, but I hope you'll come back in the discussion to ratifying or not that these five areas are where you want us to focus as a workgroup.

Latanya Sweeney – Laboratory for International Data Privacy – Director
Do you want comments now or wait?

David Lansky – Pacific Business Group on Health – President & CEO
I'd rather hold them, but if you have a good clarification, go ahead. Okay. The other point is the Quality Measures Workgroup has not yet received the reports from these tiger teams, so today you're getting a preview. This has not been discussed, vetted, validated by the full workgroup at all because we're moving really quickly. There are only three or four weeks of discussion. We do have a meeting late next week of the workgroup to review the report you're hearing today, probably with a little more detail, and so this is a great time for you to react to what you're hearing in this preliminary report and help the quality workgroup anticipate some of the issues we need to be thinking about, as we take the full report in next week.

I think the last preparatory comment I would make is that we need to think about how these measures that will emerge in each of these categories will really be used in the field and how they'll be used by CMS or by private interests or others. What is the value in producing this kind of information? Does it end up in the core menu reporting set? Does it end up in somehow influencing PQRI or other pay for reporting or pay for performance systems?

With that, let me walk you through the work to date. We'll just take each of these five areas separately. In the sixth copy of your handout today, you'll see a different version of the slides you're about to see, and the main difference is you see a lot more granular detail about example and sample measures in the printed copy, and I would ask you both to ignore it, but glance at it. The various subcommittees through up examples to illustrate their thinking. These are in no way endorsed, accepted, going anywhere. They're just examples the committees wanted to use to reflect what the kinds of things they're talking about.

The care coordination tiger team has identified four sub-domains underneath care coordination that they believe would be appropriate candidates for meaningful use criteria, clinical quality measures, whether there is an effective care plan in place, that there are measures of care transitions being successfully handled and managed, that there's been appropriate and timely followup, and that interventions are coordinated, and they give several examples in this text here. I'll let you glance at that for a moment and think about does that high level set of sub-domains look like an adequate representation of the concerns we would have about whether care coordination is being achieved.

They then took that set of sub-domains, which you now see on the left side of this slide, and the text definition associated with it, and then they began to sketch measurement concepts, which would lead us toward the actual measures of this sub-domain. So for example, in the notion of having an effective care

plan in place, a measurement concept is, is there a comprehensive clinical summary in place. Is there a self-management plan in place? Is there an advanced care plan in place for appropriate patients? Is that a palliative care plan in place for appropriate patients?

You could then imagine, as the next step going farther to the right, if you imagine this spreadsheet growing, a set of actual measures that are operationalized for each of those measure concepts. Just to replay, the set of tasks we've given ourselves is to identify high level domains like care coordination, sub-domains like those you see here, concepts that go with those sub-domains, and eventually measures that go with those concepts. What we will be asked to approve next week are the sub-domains that you see here and the measure concepts.

The next grouping is care transitions. Here you see measurement concepts associated with transitions like several elements of successful care transitions, transitions between settings of care, the patient's experience of the transition, and potential outcomes of unsuccessful transitions. One issue, obviously, we'll have to come back to is how do we have a parsimonious set of clinical quality measures that get as much of these concepts imbedded in one beautiful measure rather than four measures or eight measures, as implied by this slide, because quickly you'll see, as we go through this slide deck, just in this domain alone, we would end up with many, many measures. I think, as Christine said earlier, perhaps there are some elegant ways to capture the substance of these concepts without having a measure for everyone. We'll certainly want to explore that.

Still within the care coordination high-level domain, two more sub-domains: appropriate and timely followup, and intervention coordination. You can read here the concepts that would attach to these sub-domains. Let me roll through. Just visualize. You can just kind of take a minute and read each of these as we go through them. Obviously this won't be the place to debate and refine all these, but I think what we want from you is a reaction to the structure and approach and the level of detail that we're already drilling into.

The next big topic is efficiency, including both underuse and overuse. There are five sub-domains here. Person centered care, that is the affect on the patient as they move through the care delivery system, hopefully in an efficient manner. The use of affective care, practice guideline-based care that is presumed to be associated from a process point of view with efficient care.

The idea of having longitudinal care dashboards that would encompass the span of care for a particular type of patient, a particular condition. Value-based population and preventative health that is deploying interventions, which are known to lead to long-term population level value. Then appropriate care, this text mentions both under-used clinical tools or stinting of care, but we're also discussing overuse or inappropriate services being deployed. Then you see here some measurement concepts for those sub-domains like readmission, use of diagnostic imaging, appropriate use of diagnostic imaging, medication, generic use, the leading condition categories, and so on.

The next high-level bucket is patient safety, and here there are three sub-domains identified: medication safety, hospital associated events, and falls. Then you see the measure concepts on the next slide, number ten, associated with those sub-domains. The next grouping is patient and family engagement. Here we have five sub-domains: patient activation or self-management ability, whether patient preferences are honored and patients are involved in shared decision-making, whether patient reported health outcomes are being measured and achieved, whether the patient is being connected to health related resources in the community, and whether family and caregivers are involved in their care as appropriate.

Then there's a set of measure concepts attached to each of those. I'm on slide 12. Then on slide 13, additional measure concepts attached to each of those areas. Not surprisingly, many of the ones in this patient and family engagement domain would require getting data from patients, not only from the EHR.

Then population and public health has three sub-domains: healthy lifestyle behaviors, effective preventative services, and health equity and reducing disparities. Just to highlight in this example of preventative services, you've heard that phrase about three times earlier in this slide deck. There's an example where the ultimate resolution of this hopefully would be a measure or a set of measures that address this through several domains, not just this one. We we'll certainly try not to multiply and duplicate measures.

We've mentioned to you earlier that there's an expectation of putting out a request for information to the community of both providers and measurement folks. That would be an opportunity for them to respond to us with elegant and parsimonious ways of addressing these concepts from the measurement expertise community rather than having us try to figure all that out around this table. Here are the sub-domains attached to population and public health.

Then the last tiger team, which has not yet convened, would address several methodology challenges that have already surfaced this morning in our other discussions around how do you construct measures over time, longitudinal measures. How do you construct delta measures of change? Capturing adverse event reporting, which may happen outside of the scope of the EHR. In addition, the methodology issues around patient-based data, patient sourced data are being discussed in the patient engagement tiger team that Christine is chairing.

That's plenty to take in. Why don't we pause there and just have a kind of—let me go back in slide land to the earliest structure. I know Latanya, I'm sure others, have thoughts about this overall framing. Hopefully now you've seen the map that we're trying to walk across, and we welcome your input on how we're tackling this charge so far.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Latanya?

Latanya Sweeney – Laboratory for International Data Privacy – Director
Yes. Actually, I think it's fine. I like the general idea and the effort that's put in. But I really think you should consider two more, and that would be privacy because we can do the same kind of domain and measure concepts, and that would include things like breach notice. We could figure out what the set of the right concepts are. You could actually think of that as HITECH. The other one should be information exchange. So to what extent is— There might be more of a technical measure, but still what it would do is it begins to take the whole space over which these machines are operating or which the IT is operating, and you consistently are just sort of applying the same kind of metrics in terms of overall approach.

David Blumenthal – Department of HHS – National Coordinator for Health IT
David?

David Bates – Brigham and Women's Hospital – Chief, Div. Internal Medicine
I like the framework a lot. I think it was a great idea to establish these teams and to get more people involved in doing this work because there's an enormous amount to do. On the care coordination piece, which is the one that I know the best, I like the framework a lot. There were several specific recommendations that came out of our group that I can't quite see that I think would be useful to include in future recommendations that I don't see how they fit into the framework. But I think that things like that can be reconciled down the road.

David Lansky – Pacific Business Group on Health – President & CEO
I think I probably should have gone to the very last slide just so that we can think about this question of how do we—sorry. I got people excited—decide the work from here once we get through this discussion of identifying whether these were right domains, sub-domains, and concepts, and the tiger teams and the Quality Measures Workgroup, as you see here, vet those in the next couple weeks. Then we'll come back to you with a recommendation that goes out to this RFI process in November to identify measures in

use for measures that need retooling that would fill these areas that we're talking about. That would then give us new information of what's out there in the world, and hopefully give us enough to come back and shape an actual RFP to procure or support those who could give us the right measures.

To David's point, I want to raise this third bullet here because I think there's an opportunity to take these high level concepts we're looking at today and essentially send them out to the larger community and have experts like David Bates and others come back and say here's a way to address these measurement constructs that you're interested in based on the work that we've done in our institution or in our program that'll then drive us forward. I hope a lot of the tiger teams have been receiving input of the kind David suggested that are really interesting ideas of elegant ways to capture data and report on quality that hopefully we'll get more of that from the larger community once we get to that stage.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Neil?

Neil Calman – Institute for Family Health – President & Cofounder
In terms of the major domains, I think we need to call out a domain around measures around health disparities. We've put that out there in the title of one of our main objectives, and we don't really have any measures around that, so there are two ways to do it. One is to call it out as a separate, major domain, and the other is to make sure that we identify within this since we're requiring people already to capture information on primary language and race and ethnicity to capture some of the measures in some of these other areas that we would want reported based upon race and ethnicity and primary language to see if there are disparities that are evolving. They could be around care coordination or clinical quality or safety or any of these other things. I leave it up to you to figure out where it best belongs. But right now it's missing.

David Lansky – Pacific Business Group on Health – President & CEO
I would say that particularly the population and public health team has done a considerable amount of work on the disparities issues within their sphere, and it might be appropriate for us to challenge the other groups to do something similar and maybe look at the work from the population health group as a model.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Gayle?

Gayle Harrell – Florida – Former State Legislator
I just would like to caution everybody on the group that when you determine these measures, first of all, that you make them broad enough so that 99% of providers have the ability to qualify that it's specialty dependent, that it is very broad in the sense that there is the ability for someone, for every physician, every provider out there to quality. Also that it is a minimal number of measures, and that those measures are not over-burdensome for most to get within the record. You know, we had the whole discussion previously on numerators and denominators, and you want to make sure that these are parsimonious enough, and they measure what you're capable of achieving. So we've had that discussion before. '

Also, I think that we need to make sure that as this goes forward, that it covers all spectrums of everything that we want meaningful use and the meaningful use is what is to determine the measures, I believe, is where we are going, that especially the privacy and security measures. I think Latanya was very wise in saying that. And those parameters we set out at the very beginning that we wanted to achieve, and one of them absolutely was privacy and security. I believe that they very much need to be included within it.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Marc?

Marc Probst – Intermountain Healthcare – CIO
Just a concern. Not a concern. Just a statement that there are other organizations looking at measures, the joint commission and other groups. It would be nice to know that these are well aligned. That we're not creating either slightly different measures, but measures that are being done in other areas, and that kind of goes back to the conversation we had with meaningful use toward the end. I am getting kind of a visceral reaction that tiger team means more work, and so can we stop having tiger teams? I mean, I'm just being funny, but maybe not that funny.

The concept of tiger teams, I mean, they really are creating a lot of detail in this, and I will tell you, on an annual basis, we as an organization will take one or two of those measures and really try to drive them down because we look at our community, what's happening in that community, and what's going to provide the best care or the best outcomes for the community we're dealing with. I'm a little concerned that if we throw 40 measures out there that we're going to try and attack 40 measures and never really achieve that benefit that we'd like for the community that we're serving.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Paul? Just Paul, then the other Paul.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Thanks, David, for this work. One of the things, as the Meaningful Use Workgroup talked about moving towards outcomes, we've put a lot on the plate of your workgroup hoping that you would save us. It looks like a lot of these measure concepts anyway are more structural and process oriented than the outcomes that we all envisioned. Now that's accepting the caveat that David Bates said, which is, well, there aren't a whole lot of them, and that's part of it.

Maybe one approach is, and there is a patient engagement tiger team. Have you thought about relying more on the patient to provide the outcomes of each of these facets like care coordination, for example, rather than some of these process and structural measures? That's just more of a comment and a little bit of a question.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Paul?

Paul Egerman – Software Entrepreneur
Thanks. It was a great presentation, David. I just had a question about something you said. Maybe I didn't understand it right. Did you say that some of these measures will not come from the EHR?

David Lansky – Pacific Business Group on Health – President & CEO
Yes. Even as Paul Tang just suggested, we may use measures from the patient to assess whether the EHR is leading to improvements in clinical quality and in outcomes.

Paul Egerman – Software Entrepreneur
How do you gather that information though?

David Lansky – Pacific Business Group on Health – President & CEO
That's a methodology question we're also talking about. There are surveys like CAPS and others that are out there now to capture data from patients. The methodology question is what kind of samples do you draw? Who is included in terms of the denominator? Which physicians are assessed and so on? There would be a lot of challenges to implementing it for the purposes of a significant payment incentive. That's what we'll talk about.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Deven?

Deven McGraw – Center for Democracy & Technology – Director
As much as I appreciate the emphasis on privacy in this last conversation, and completely agree that we need to give it some attention in the next stages of meaningful use, I'm not sure it belongs in the Quality Measures Workgroup. I actually would wonder, suggest that the thinking about the next stages of meaningful use in the privacy area is probably better taken up not in this set of tiger teams, but by the other tiger team that we have to deal with privacy and security issues.

Latanya Sweeney – Laboratory for International Data Privacy – Director
I was just saying that this is a different kind of thing.

Deven McGraw – Center for Democracy & Technology – Director
Yes.

Latanya Sweeney – Laboratory for International Data Privacy – Director
Addressing a different kind of quality measure in the same way patient and family engagement shows up in meaningful use and has other requirements. The kinds of things that can come through here are not the kinds of things that the tiger team would necessarily address, nor necessarily the kinds of things that meaningful use would address without sort of having this kind of deep dive. I think this is a very attractive way to get a lot of data, a lot of measures. At the end of the day, you're probably not going to want to do all those measures, but it's a very different lens to look at this space about what is measurable, how do you measure it, and so forth, and which of those measures could coincide with some of the others.

Deven McGraw – Center for Democracy & Technology – Director
Right, which I think is actually a fair point. I think I was just interpreting you and Gayle to suggest that these groups start thinking about privacy and this workgroup versus thinking about an approach, a measure based approach, which is to privacy that may be a new way of thinking about meaningful use. Am I understanding you right? Are you asking suggesting that these people take it on?

Latanya Sweeney – Laboratory for International Data Privacy – Director
I'm not saying that each of those should take on privacy. I'm saying privacy should be one of those.

Deven McGraw – Center for Democracy & Technology – Director
In the Quality Measures Workgroup?

Latanya Sweeney – Laboratory for International Data Privacy – Director
In the quality measures, the same way that patient and family engagement is a quality measure because there's a whole discussion about how do you measure privacy. There's a whole community that discusses these things, and it provides a totally different kind of insight.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Mike?

Mike Klag – Johns Hopkins Bloomberg School of Public Health – Dean
I think the framework is a good one. I share Paul's concern about, in a sense, unfunded mandates. You didn't say it that way, but if you specify data collection that's outside of the electronic record, who pays? How does it get done?

But I wanted to comment on the population and public health. I was struck there. Somebody mentioned that many of these are process measures. But in population and public health, they're almost all outcome measures, at least the examples. Looking at process measures and reporting of reportable diseases, communication with health agencies, the workgroup might consider looking at those as process measures.

David Blumenthal – Department of HHS – National Coordinator for Health IT
I want to make sure a contextual comment here. They've been raised; some of my points have been raised implicitly or directly. First, this is a very broad engagement on these issues, but we're going to have to focus back down because the thinking that's going to go on here is going stir a lot of reflection and a lot of ideas. But eventually we're going to have to say, as a group, that we think certain of these measures, by no means all of them, but certain of them are so important or so capture the value added by electronic health systems that they're important to be included in meaningful use. Also, will shed light on the way in which measures that will be collected or have been collected through claims data or chart review can now be collected electronically. I don't think the point of this exercise is to reengineer quality measurement so much as to direct the traditional work of quality measurement into the electronic environment and adapt it to the electronic environment, and potentially identify a few, a parsimonious set of measures that were impossible that are very persuasive, very compelling, and were impossible to measure in the paper or claims world.

Just to remind you, there is a different activity going on, related activity going on to create electronic specifications for the PQRI measures, the so called RAC … measures, other NQF approved measures that have not been electronically specified. That's going on. So they will be available for choice. A lot of them are specialty related, so there will be a much more robust, complete set of specialty measures that can be collected electronically.

Where I think we have something special to add is by saying these are critical concepts, and now the electronic health record enables us to collect them more efficiently or to collect new measures that are really, really important now that we have electronic records. I think we don't want to recreate all the work of quality measurements going on everywhere else. We're not constituted to do it, and we don't have the expertise to do it. Yes, Latanya?

Latanya Sweeney – Laboratory for International Data Privacy – Director
I was just going to clarify, just to be clear, when I think of the kind of work in the Privacy and Security Tiger Team and stuff like that, it's really important work about framework area. But when I think about quality measures, and when I think about meaningful use, I think about what incentives. What kind of function incentives do I want to add?

When I think about quality measures, it tells me how good did we do? I can actually think, and there are lots of great models for how do you model trust? How do you match security features to security outcome? We don't actually know those, and sometimes what the privacy team working group has struggled with is difficulty finding the ground, and so having a Quality Measures Workgroup could be extremely helpful and insightful to what's important.

David Blumenthal – Department of HHS – National Coordinator for Health IT
The quality of care has a traditional realm in healthcare measurement, but measurement extends well beyond quality … you can measure that … about quality might cost, and so I don't think that not including privacy and security in the quality measure group means you wouldn't or couldn't measure it.

Latanya Sweeney – Laboratory for International Data Privacy – Director
Yes, but it fits nicely with the patient and family engagement, the kinds of things that were described as the concepts. There's some really nice ways to measure it that would fit in, whereas if you did undertake an activity, some of the activities wouldn't require extra dipping of resources. You could leverage off of some of it. I understand that it's not what this community normally thinks of as quality measurements. Other communities do, and so there's a lot of prior work elsewhere to leverage. To say that privacy and trust are our goals that we want to measure how well we're doing.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Christine?

Christine Bechtel – National Partnership for Women & Families – VP
As I'm thinking about this, I think it's worth the exercise. I don't think we have the right people on the patient and family engagement tiger team necessarily. We've got people who are identified as experts in domains like shared decision-making and patient preferences. But I think it is worth thinking about the role that technology plays, and privacy and security play in patient engagement and trust, and this is an area that I am absolutely unfamiliar with in terms of the field that's already been thinking about how you measure trust. So I think it's worth some further thought.

I don't know, and don't want to prescribe how to go about that, but I think it's worth some thought in conjunction with the Privacy and Security Tiger Team just to suss out what are some potential options here so that we can have a better, concrete sense of whether it's appropriate for this piece, whether, as Deven was wondering, if it's more appropriate for meaningful use functional criteria and potentially measures that CMS could use in the framework we already have around CH2. I don't know where it fits, but I think it's worth some further exploration.

David Blumenthal – Department of HHS – National Coordinator for Health IT
This was mostly an informational exercise rather than requiring us to react, so since we have not had a break, and it's noon and lunchtime, Paul, yes?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Yes. I fell down on the job as far as getting approval of minutes, but I think being before lunch can help this activity. But so if anybody – I'd like to entertain a motion for approving the minutes of the last meeting.

M
Motion to approve.

M
Second.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Second, and any discussion? All in favor?

M
Aye.

M
Aye.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
And any opposed to abstained? Good. Thank you very much.

David Blumenthal – Department of HHS – National Coordinator for Health IT
We'll reconvene at 12:45.

Gayle Harrell – Florida – Former State Legislator
Great.

(Break for Lunch)

Judy Sparrow – Office of the National Coordinator – Executive Director
The meeting is ready to adjourn, please take your seats. I mean start, wishful thinking.

David Blumenthal – Department of HHS – National Coordinator for Health IT
David, are we calling you back for service already?

M
No, fortunately, no.

David Blumenthal – Department of HHS – National Coordinator for Health IT Micky, thanks for coming back to talk about information exchange. I look forward to your report.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
Today, I'm delighted to be here. Today, we're going to report on a particular activity that the Information Exchange Workgroup has been working on, which is provider directories. I wanted to start off with some high-level principles, really just getting to the end here. What we would like for a consideration of the committee is the high-level principles that are going to guide our work in the coming months as we get deeper and deeper into making a set of recommendations related to provider directories.

Let me just start off here at a higher level. The charge to the Information Exchange Workgroup, I think that the committee has seen this many times now, is kind of two focus areas. One is looking very practically at breakthrough areas where policy barriers might prevent providers and/or states from moving forward with respect to health information exchange. The second is being a conduit for things that are happening on the ground and trying to keep an ear to the ground, understanding what's going on as states start to move to their implementations. As vendors and physicians start moving forward, understanding what issues there might be there and seeing if those can be synthesized into the policy recommendations as well.

This is the membership of our workgroup. A number of members of the Policy Committee are on the workgroup. I want to thank all of the members of the workgroup for sloughing through a lot of conversation about provider directories as we'll discuss. Also want to give a very specific thanks to Claudia Williams, Kory Mertz, and Judy Sparrow for all the support we've been getting from the ONC side as well.

Today, I wanted to focus on provider directories in particular. We have a task force, we'll describe that in a second, give a little bit of background for the issue, talk about the workgroup perspective on policy objectives and the problem statement. What problem are we trying to solve here? Then finally, propose some high-level principles that we would like to use to guide the work going forward.

One of the things that I think that all of us have experienced as we've dug into this is you start off with a topic like provider directories, and I know everyone is thinking that is an incredibly sexy topic and I really want to be the first one to be on that workgroup. We actually had a large fraction of the workgroup actually volunteer to be on the task force. One of the things that we are going to do is launch two task force in parallel, one in public health and one in provider directories. When it turned out, a lot of the members of the workgroup were on the task force of provider directories. We said, let's just focus on that one now.

The other thing I think as we dig into that, as you look at that and you think, that's something we could really get our arms around. Provider directories, it's a very important thing, we ought to be able to get our arms around it. Of course, like a number of these issues in our very complicated healthcare system, as you start pulling back the layers, you discover that it is very, very complicated. Certainly, I'm as guilty as anyone of wanting to jump to conclusions and jump to solutions. I think what you're going to see here is more of a laying a foundation of, do we all understand the problem? What is the background? What's going on in the market today? Finally, what are some principles that can guide that push to recommendations and push to propose solutions over the coming months?

The high-level roadmap here for the rest of the calendar year is today to talk about high-level principles. Then at the November Policy Committee meeting, we would like to come back to you with what we're calling round one recommendations. So we're sort of staging our recommendations here. Round one recommendations will be focused on what we're calling entity level directory services. We'll describe this in a little bit of detail in a second.

Then round two will be more on best practices recommendations for sub-national players—states, regions, others—who are interested in developing what we might call a broader discoverability resources. You'll see the dancing around a little bit with the terminology reflects that we, ourselves, need to do more work on specifically defining key terms, which is work for us to do I think. I apologize in advance that we're not as far along as I think we would like to be in terms of defining some of our key terms. But that's sort of the rough roadmap here of what we would like to be doing over the next few months.

We launched a Provider Directory Task Force, very ably led by Jonah Frohlich from the California Health and Human Service Agency and Walter Suarez from Kaiser Permanente. I believe both of them may be on the phone. So they're certainly available to add any color along the way and also to help respond to questions. They've been terrific in terms of the time they've spent leading us and the workgroup that you see here or the task force that you see here in these conversations.

Starting just with some background on the issue itself, the cornerstone of the foundation, kind of a facts set that we want to establish here for the Policy Committee as we think about this going forward. First off just understanding that health information exchange especially in the direct exchange kind of scenarios, where you've got a sender conveying an unsolicited communication to a known recipient, occurs today with high frequency.

As we know it occurs in multiple modes, fax, phone, mail. We're electronic, it happens through a variety of channels. You can have employee service networks, like SureScripts, Quest, LabCorp, EHR vendor networks are growing. So Epic, eClinicalWorks, others have their own networks that connects up their own installations and starting increasingly to connect up others. Then health information exchange organizations, just to name a few. This isn't supposed to be a comprehensive list.

Directories perform a key function in any of these kinds of transactions. Essentially, if we're going to give just a bumper sticker kind of definition to a directory, it maps what we might think of as human friendly information to machine readable information. Such as a person's name to a phone number for example, just a very easy and commonly understood idea of a directory, or an Internet domain, to a domain name, to an IP address. So when I say HHS.gov, which is human readable, translate into an IP address that a machine can understand. Those play key critical roles in making exchange easier and more scalable as you think about it.

Most directories right now are proprietary and local and specific to a particular mode of exchange, whether it's the directories that we have just in our Outlook or Eudora or what e-mail client you use. You've got a directory in there that you, yourself, have populated personally or your organization has helped to populated with an organization address book as it were, but it's held locally and it's maintained locally. Or you can have network specific directories as you rise up into levels. Certainly, SureScripts, integrated delivery networks, health plans, health information organizations, all of them have very specific directories that they've created for very specific business purposes. The most well-known nonproprietary cross organizational directory is the distributed DNS registry system that's used for Internet routing. I think most people are more or less familiar with that system. It's one that we'll come back to as we talk about directories.

A final point that we want to make sure that everyone understands is that health information exchange, and particularly directed exchange transactions, and I've made that capital for a reason and we'll talk about the definition of directed exchange next, it will continue to grow regardless of whether the federal or state government action is taken on provider directories or not. In a way, provider directories are a way to

automate things, to make things more scalable, to make things easier, but they're not necessary to exchange because they're being developed privately for private purposes and very specific purposes right now.

A variety of exchange approaches are likely to be available to clinicians as we have more certified EHRs that enter the market, and as the ... the meaningful use incentives start to kick in. However, it is our sense, despite the fact the ... statements that it'll continue to grow regardless of whether we do any work or whether we come to any conclusions here is that the adoption state will almost certainly be hindered by a lack of uniform and ubiquitous approach to cross enterprise, cross platform exchange. Provider directories can play a key role in that, not the only role, but a key role. So that's a little bit of the foundation that we wanted to lay before we dive into this.

We did some fact finding. We had a public hearing on September 30th that brought together industry experts, who we assembled into four panels. There were two that were focused on business requirements. So we structured the data to say, let's first talk about those who have some business requirements related to directories. Then let's move to state and regional framing of the issues as they're seeing it. Then finally to some technical requirements on how we might be able to think about approaches to address those business requirements.

Some of the common themes: It was a very full day and a very busy day, so we're just trying to draw out the common themes here. There was a lot that was discussed and a lot of rich detail. But the first in a way of a common theme was that we ought to be distinguishing between what we're putting in quotes here. This is where I'll apologize again for not having clean and crisp definitions around these things because we keep revisiting the definitions as we get deeper into the conversation. But I'll put quotes on these right now and hopefully that will characterize the two areas that we're thinking about.

One is distinguishing between what we're thinking of as an entity-level versus a clinician-level directory. Entity-level directories in a loose definition right now is essentially a directory that serves to automate routing of information among addressable network nodes. At the entity or organization level that is an addressable node, meaning a node on a network. Whereas a clinician-level directory could serve automated or human look up kinds of functions at a clinician level specificity. So if I'm talking about a Dr. John Halamka at Beth Israel Deaconess Medical Center, the entity level would be Beth Israel Deaconess Medical Center, where the clinician level would be Dr. John Halamka at Beth Israel Deaconess Medical Center.

Another theme that came out is that we should support interoperability across states and regions and leverage what works in the market today. Another is that we want to be able to align with the meaningful use stage one transaction needs first and foremost, because those are what's immediately being presented to us, and certainly, the immediate barriers to there. But we want to be open and flexible to stages two and three and beyond.

Then finally, we want to be cognizant of the role of and perhaps the needs of NHIN Direct. Not that that's our focus, but to the extent that what any recommendations that we can have, can better enable that in the market if that is going to be a viable solution to solving the number of directed exchange kinds of barriers right now. That we want to be able to be supportive of that.

Second, drilling down a little bit into some of the themes. One is that entity-level directories should be the first priority, and that a focus ought to be on what people started talking about as a thin layer of discoverability for entity-level directories. Which would not be at the clinician level at the outset, because of complexity and a better definition needed of what the requirements might be, but there's a lot of complexity once you get down to the clinician level in particular when you start to think about that.

At the entity level, there's three key components that came out from that hearing as being very important as we think about entity-level directories, one, finding a standard addressing scheme. So is there some

consistent way, I mean e-mail is a great example, but we have a consistent addressing scheme for e-mail. All of us know it, all of us understand it, that doesn't mean that we know every e-mail address in the world, but we understand the basic structure of it and it's very familiar to us.

Another is establishing basic discoverability of an entity. Meaning how do I understand that a particular clinic, how do I get from that understanding of a clinic in wanting to deliver information to a clinic? Because that's where a patient is getting their next care, into an IP address, meaning that I can deliver it from machine-to-machine. Also that have some understanding of what services are supported by that entity. So can they actually receive a CCD-C32 document for example if it was sent to them? Is there some way of being able to discover that?

Then finally, basic discoverability of entity security credentials. Where the idea there is if a directory can at least provide information that security credentials are in place so that the message can be sent; not for the issuance of those credentials or for the management of those credentials, which is really what the Privacy and Security Tiger Team is going to be more focused on. But once those are established that they exist and that they can help facilitate them, the transaction, because we know where it's going and we know that the security credentials are in place, that that would be valuable as well.

Then having common requirements for these entity-level directories that really should be defined with what we're starting to call rigid conformance at the national level. That people started to reflect and have some consensus around the idea of entity-level directories being relatively high level, but very useful in a variety of ways. Also being something that we might be able to get our arms around having a national level approach at the entity level.

Once you go down to the clinician level, again, this is all reflecting what we heard in the provider directory hearing, that would certainly seen as important as well, but likely to be much more complex. That the individual clinician level you start to get to clinicians being in different places. Also the fact that what we're talking is messages going from machines-to-machines, not the machines-to-humans. I mean at the end of the day, humans need to be able to have access to it and read it, but that we're talking about machine-to-machine. That starts to present another complexity as we think about this.

The development and implementation can certainly be at a sub-national, regional, or state level as we start to think about clinician level. In part because the information as you go further and further down into the organization and at the clinician level, that information is much more readily available and much easily to think about at a more localized level. Particularly, when you think about all the turn that goes on in the market.

Then finally, an idea that perhaps you don't need, what we're thinking about as rigid and conformance as you move down to that level. That perhaps you have an entity level, which has more concrete requirements, and you allow a little bit more flexibility as you start to think about federation as you start to think about state level sub-national entities.

That was the background of our depiction of what's there on the ground now, the fact finding that we got from the industry experts we brought together, and now thinking about the policy objective and the problem statement. The policy objective, again, we keep reminding ourselves is to facilitate the rapid increase and secure electronic health information exchange throughout the health system. Again, just going back to the point that whatever we do, the industry doesn't need this to move forward. What we want to be able to do is to help in whatever ways possible to accelerate what is going to happen. But it's not that they need state or federal action on provider directories in order to make this happen.

With that said, there are some issues that we think are amenable to some recommendations. The lack of a consistent approach to cross organizational provider directories will be a barrier we think, both in terms of directed exchange, as well as in health information exchange more broadly. I think you already start to

see it in the market as vendors start to think about going across platforms, as we start to think about cross regional kinds of exchange.

We also, without any action, will almost certainly will represent a missed opportunity to align multiple activities and common multiple streams of funding that could yield a lower cost and a higher quality of service at the end of the day. As we think about state level HIE grants, Beacon grants, Medicaid, public health, all of them are thinking about investing in some way in provider directories at some level. That's not even mentioning other private entities that invest on their own in directories. But just looking at the publicly funded programs right now, there's an opportunity to bring some of that together if we had a more unified approach to how that could work. There's certainly some practical issues in how you bring those fundings and programs together, but without a unified approach to it, we can't even get to the conversation about how you can pull money across programs for example.

The key questions that we've come up with that we want to investigate going forward are, first, how can provider directories accelerate information exchange? What's the role that provider directories play in directed exchange and health information exchange overall? Given that role in health information exchange generally, what role can they play to accelerate information exchange? Because there's a lot of other pieces there that aren't specifically addressable by provider directories.

Second, what can federal and state governments do to guide directory development to support meaningful use and drive system wide improvement? There may be certain things that provider directories could do to accelerate information exchange, but it may be that there really aren't any good policy levers to do those things, and you hope that the market will move forward. We want to be able to specifically say, what levers that we could actually pull from a policy perspective.

Then the last two points are really variations on the theme of what policy actions can be taken to promote creation of directories that will accelerate, that secure information exchange within jurisdictions, we can leave loose right now the definition of jurisdiction, and across state boundaries and nationwide as we think about that? So this is the policy objective and the problem statement.

What I'd like to do now is to dive down into a little bit of deeper consensus view from the working group on the principles themselves, and then maybe I can pause there and see if there are any questions, or I can pause now, if people have questions now. Christine, you look like you're—

Christine Bechtel – National Partnership for Women & Families – VP
No.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
No, okay. Why don't we move forward then. The first recommendation coming out of the workgroup is that priorities should be given to provider directories that facilitate meaningful use stage one transactions. In particular, we're focusing on what we're calling and we're trying to keep our definitions consistent with what the other workgroups are using as definitions of directed exchange.

I know Paul and Deven are going to be coming on next to talk about directed exchange/indirect exchange. We're trying as best as we can to keep our definitions specific. But we've proposed being focused on directed exchange transactions that are in particular of the form of PCP to or from specialists, ambulatory clinician to or from hospital, ambulatory clinicians to or from laboratories, and then hospital where ambulatory clinicians to or from public health. There are other directed exchange kinds of transactions that are there in meaningful use stage one, but these are the ones that seem to present themselves as being most in need of some type of facilitation from a more unified and standardized provider directory approach.

In general, as we think about direct exchange, the two overarching problems to solve, aside from where provider directories fit into that, are one about just discovery. So you think about a primary care physician

wanting to send a referral to a specialist for example, assuming they're both on certified systems already. You still have the problem of, I need to know what kind of messages the recipient is able to consume, meaning what kind of messages can I sent to that provider and what will they be able to consume on their end?

What mode of communication should I use? Because there's still no standards around transport, so there's multiple ways that that can happen. How to identify both the correct recipient and their address for a given mode? So just one of the things that Art Davidson and I were just talking about, how do I know, I may know, the patient may have told me as the physician. In this case, I'm referring to a specialist. So in this case I actually know who the patient is, I know who I'm referring it to, but I still may need to know, well exactly how do I address that? How do I actually get it to them?

Security is the other piece of that. The other thing that's needed for directed exchange, a, for authentication. I need to verify that the recipient computer has appropriate security credentials at the end of the day. We're talking about it going to a machine that has the security credentials, that according to a local organization or whichever organization is hosting the machine, is representing that all of the security is in place for that to be appropriately accessed by whatever users they're granting to have access to that system.

Then transport, we need to have a secure means of transporting that. There are multiple ways of doing that, but I need to be able to choose one of them. As we think about that as a broad set of things that need to be figured out for directed exchange, the pieces on the top related to discovery are the things that seem to be more directly addressable by provider directories. Then things like authentication and transport can be supported by provider directories, but aren't directly addressable by them.

As I was talking about authentication for example before, the discovery of security credentials could be something that's a very meaningful information to have in the provider directory. But we don't see the directory as necessary as being a certificate of forwarding in any way for example, and for the management of those credentials. Again, the Privacy and Security Tiger Team is more focused on that.

I'm going to skip ahead and then I'll jump back, but I want to skip to the principles now, the high-level principles as we're thinking about this. We've divided the high-level principles into two categories, one is, standing here at the very beginning of diving down into a very complex area, we asked ourselves, what initial principles might apply generally to provider directories across the board without getting into the specifics of what a particular instantiations of directories that we may be talking about? Whether it's centralized or federated or whatever it is, entity level or clinician level, are there principles that we could say right now how to apply regardless?

What we did is draw from the health IT strategic framework and the privacy and security principles that are in there, which we understand are used for a different purpose, but as we thought more about it, they seem to apply here as well. You think about those five categories of saying that whatever information is contained in a provider directory that's going to be used for clinical purposes, it ought to be open and transparent with respect to the policies, procedures, and technologies that are being used.

It ought to have a collection use and disclosure limitations on the information that is in there. That the data quality integrity are incredibly important as we start to use it for clinical purposes. It needs to have appropriate safeguards obviously and it needs to have accountability over the content that is there, timely. That follows all of those issues. Those seem to be some core principles that we can all agree to at the outset for any type of directory.

Then we thought about a second set of principles, which were really more about how should the Provider Directory Task Force and the Information Exchange Workgroup think about recommendations development going forward? This is a set of principles for us as we think about the problem. It is really

driving from the fact gathering that we did from the provider directory hearing, as well as from other kind of background work that we did. So those are a few categories.

One of the things that came through loud and clear in the hearing was that whatever we think about with respect to directories, they ought to be thought about in the stream of a business process. That what we don't want to be thinking about is creating a directory or a registry for the sake of creating a registry or directory. One of the things that a number of industry experts pointed out to us was that directories are always a bi-product of a business process. It's actually a business process that's being conducted and the data that is needed for the business process, then gets put into a directory to help build scale and to make that process even better overtime. So that seem like a good core principle for us as we think about this. Another is the focus on meaningful use, which I've already talked about.

Agility, which we heard from a number of different voices to say, whatever recommendations you make, just remember that it can't be brittle to the current circumstance. It's got to be something that doesn't get overdesigned to early and needs to remain flexible to the change coming on every dimension as we know it, whether it's health reform, technology, business organization, all of that is changing as we know. That it ought to be incremental, whatever our set of recommendations are, thinking in incremental terms to things that are actionable and achievable that build a roadmap, but have some near-term steps that one can take to start to solve some real problems in the near term with an eye toward what we may be able to accomplish over the long term. But getting back to the point of agility, you don't want to now say, we have defined the roadmap, the absolute concrete roadmap for the next five years, knowing that in two years a number of things could change.

Collaborations, that it really ought to be an approach that encourages sub-national, whether it's regional, multi-state, as well as national initiatives, to leverage purchasing, policy, and regulatory opportunities. Then in some way it ought to be complete to be able to clearly delineate both the sources and the uses of the information, as well as who might be the users, and those can be two different things. There's obviously a correlation there and an overlap, but you could have two different groups here thinking about sources of data on the one side and then users on the other. Then security as with all of this. PHI must be transmitted securely with the assurance that actors participating will adhere to a minimum set of standards to protect that information.

Let me pause here to see if, certainly if Jonah or Walter if you're on the phone, if there is anything else you wanted to add. There are a number of Policy Committee members who are also members of the workgroup, if there is anything that I've left out or anything you'd like to supplement with. After the discussion of the principles, what I wanted to do is just look at a couple of slides that talk about the road ahead. As we think about going to the next level in terms of specific recommendations, just looking at the complexities that we're dealing with and how we're thinking about perhaps scoping our thinking around that. Jonah and Walter, are you on?

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Yes, I'm on. I don't think I can add anything. I think you've covered pretty much everything very well, Micky.

Jonah Frohlich – HIT at California HHS Agency – Deputy Secretary
I agree, well done.

M
Micky, I'm going to have to leave in a few minutes, but I have a question, and that has to do with your distinction between entity and clinician directories. understand that there are fewer entities an there are probably more stable in their addresses. The question is, what's an entity? Is it for example a group practice of a certain size? Given that so much of the care in our country is delivered in what might not be entities, practice of ten or fewer, do you anticipate giving us soon a roadmap to directories or the minimum necessary directories, so that interoperability in a clinician role is possible?

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
The quick answer is, yes. We want to get some recommendations on that. Let me give a first half answer to that, but I know there are others, like Paul and others, who have more technical knowledge at this and can correct me where I've gone wrong here, but the definition of entity is obviously critical. I guess the most generic way of thinking about it is that for whatever network you have, an entity is an addressable node on the network. Right now we have the Internet, and there are addressable entities on the Internet that are supported by the DNS registry system, so that we can send something to Ford or we can send something across entities, and understand at least what those entities are.

The small practices are entities as well. I think one of the issues that we'll start to confront as we think about this is that right now as we think about the Internet, you could ask yourself, why wouldn't we just use the entities as they're currently defined? That's actually what NHIN Direct does right now. In terms of the way they're thinking about it, I think one reason you might want to have a health overlay onto that, is that when you think about small practices for example, they aren't necessarily set up as an addressable node on a network.

So I'm a physician, I've deployed EMDs or whatever system I have, which I get over broadband. I have e-mail via g-mail or whatever, but I'm not an addressable node on the network per se. Now I could become one if EMDs start to broker those transactions for me or if I'm a part of a larger system, who starts to broker those transactions for me. So there's probably a mapping there to be able to identify all the clinical organizations out there and map them to addressable nodes on the network. Some of which may be new work in the way of registering those as nodes in some way, some of it may be just recognizing the way that the market itself is playing itself out and presenting that in a way that clinicians will understand.

Paul, did I do justice to that description?

Paul Egerman – Software Entrepreneur
Yes, you did a great job, Micky. I would just also respond by saying, when you think about entities, especially provider entities, it's not just medical groups and hospitals, there's also laboratories, retail pharmacies, commercial clearinghouses, maybe these HIO organizations themselves, all might have entry to this entity directory. Then when you think about clinician-to-clinician communication, this communication really is related to really EHR systems talking to each other.

To the extent that you get clinician-to-clinician communication, there is workflow behind the EHR systems that direct the information to the correct clinician. If it's an alert about a test result or just a test result, it's actually the EHR system that somehow gives that information to the clinician. So the entity level directory is sort of like the right level for this national standard, where you get the individual clinician level interested is if somebody wants to communicate with a specific clinician and doesn't know where he or she practices. That would be a reason why you might want to have a clinician-level directory.

Latanya Sweeney – Laboratory for International Data Privacy – Director
Can also just a question and qualification on the same on the same point?

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
I'm sure I'm not going to be able to answer your question, Latanya. Go easy.

Latanya Sweeney – Laboratory for International Data Privacy – Director
No, no, no. We do the study exploring various paradigms in information exchange and so forth, and so we had also did a survey on the provider directories. One of the things that, not trying to say what they should be, but just sort of trying to better understand what's out there. One of the things that we found, this is actually a nontrivial issue of entity, where an entity is a group versus a provider.

In the CMS data for example, we find a provider might be under a provider's identity, they may be operating in multiple hospitals, and also a part of a practice. So now that same provider would have five different identities, but they're one person. They want to use their identity irregardless of which of those systems they might be logged into at that given time. So that's a complication that I just pushed out there to you.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
Right.

Latanya Sweeney – Laboratory for International Data Privacy – Director
The second thing that we found is a reason to actually pull, put it out for your consideration, to actually pull away from trying to push security and authentication into the provider directory, but leaving them independent. The main reason for that has to do with variations of by state law. So if the permissions are external to the provider directory, it makes your life really easy, and then you can do really nice flexible things with the permissions.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
Right. But certainly a federated approach might help with that allowing that flexibility though, wouldn't it?

Latanya Sweeney – Laboratory for International Data Privacy – Director
Except if they work across, yes.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
Yes, right, got it. Yes and certainly, the issue of clinicians practicing in multiple sites has come up as being an issue. I will say though, that we're talking about everyone being on electronic health records first and foremost, we're not talking about being able to have a set of business rules and directories that says, this is for someone who wants a fax, and this is for someone who wants snail mail, and this is for someone who wants EHR.

If we can constrain ourselves to just saying, it's for electron health records. You could still imagine that something could be quite workable at the entity level, because at the end of the day I'm delivering patient information to a chart that is managed by the entity. The fact that the clinician is there is something that the clinician at that time happens to be working at that entity and is taking care of patients at that entity. But at the end of the day, if the physician were to leave that practice for example, the patient's chart is still the patient's chart, and it's the entity who's responsible for it at the end of the day.

What we're doing in the next slide will sort of depict this a little bit more clearly, and hopefully is that, what our recommendation is that first and foremost we are talking about a system that delivers information to the doorstep of the entity, and that it really is the entities responsibility. If it's on an EHR, it's the EHR systems responsibility to figure out who it goes to and how it gets to that particular user, because that's going to be specific within an organization. Epic has a certain way of doing it, eClinical has a certain way of doing it, Intermountain Healthcare has a certain way of doing it. We wouldn't want a directory to be trying to unbundle that or trying to get all the way down to the user for any type of reason.

In the example of a clinician perhaps leaving and something gets addressed to that clinician. Well that would happen the way e-mail happens today, that it's up to the organization to figure out Dr. Jones isn't here anymore, but the patient whose information is being conveyed here, that's the entities responsibility to figure out how is that appropriately managed. I thought it was clear.

W
We were talking then down to the individual clinician level when you have a one-man practice, that becomes an entity at that point.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO

Yes, right.

W
So any entity, even down to the single clinician, then would have to be in that entity directory?

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
Right, exactly, yes.

W
Just to clarify.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
Yes, no, no, that's a great clarification, because even in our own conversations, we've always got ourselves tangled up by that example, where the individual clinician and the entity are one in the same. Larry?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
This is really good work and I'm going to add this, not that you should solve it, but you should just remember it. In your example of the delivery problem, it needs to get to the organization and then to the patient.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
Right. So, clearly patient identity management is a big piece of this. I don't want to derail the efforts to get organizational directories working, but we need to get it to the patient, because you're right, that's the record that we're trying to make whole.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
Right. Yes and certainly, in the entity approach, it is the entities responsibility to figure out who the patient is and who the provider is, both, because there is no universal scheme for either of those in the entity level.

Latanya Sweeney – Laboratory for International Data Privacy – Director
But Micky, I think there was—

Jim Borland – SSA – Special Advisor for Health IT, Office of the Commissioner
We've certainly dealt with some of these challenges—

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
Jim, could you turn the mic?

Jim Borland – SSA – Special Advisor for Health IT, Office of the Commissioner
A third time's a charm.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
There we go.

Jim Borland – SSA – Special Advisor for Health IT, Office of the Commissioner
In some of our early work, we had to address some of these same challenges. I just wanted—

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
For NHIN exchange, is that what you're ...?

Jim Borland – SSA – Special Advisor for Health IT, Office of the Commissioner

Yes, right. Is your approach really one at the data level of really an EHR-to-EHR exchange, is that the model that you're using or are you looking at more of a person-to-person exchange? Because they're two very different problems. EHR-to-EHR exchange assumes that the EHR itself will be the conduit through which the person, whether it's a clinician or a patient will access that information.

The challenge that we were faced with, not identifying the location of a provider, but identifying the location of a patient's records. That kind of gets to your issue about a clinician that leaves an entity, but leaves a patient's records behind. We always tried to look at this problem as a data repository identification problem.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
Yes, so we're thinking about it as I would broaden it from EHR-to-EHR as clinical system-to-clinical system. Because as Paul noted, we're talking about labs, we're talking about others, but it's clinical system-to-clinical system.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Deven?

Deven McGraw – Center for Democracy & Technology – Director
I cheated and looked ahead at some of these processes to make sure that it wasn't covered later. The set of questions that are swirling around in my mind that don't necessarily seemed to be captured here are issues of participation. Is it voluntary, is it mandatory? If it's voluntary, what do we need to put in place to encourage providers to participate in these directories? So there's a set, and then who gets to access these directories? Because you could imagine that they could be very valuable for more than just the exchange that we're contemplating here. So I think we need to fit in some space for thinking about, so if you look at question two, I think it's two—

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
Are you looking for that slide number?

Deven McGraw – Center for Democracy & Technology – Director
—or number 3, I'm in slide 9. So what policy actions can be taken to promote creation of and participation in provider directories? Because I think that broadens the lens and says, what's going to make this an attractive proposition for providers? Part of that is about, what are the terms of participation? But the other thing is, what risks am I going to experience by having my name or my computer address on this thing, and suddenly I'm getting all kinds of SPAM?

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
Right, yes, absolutely. We can jump ahead to this depiction of the schematic just very quickly and then move to the questions, which are really about what we are going to be addressing in the work ahead. One of the great things about doing a laundry list of questions like we're going to have in the last slide is, I can easily say, "Oh, Deven, that's all covered." No, but I think those are real questions. I'm at least as guilty, if not more guilty than anyone else on the workgroup of wanting to jump to those kinds of questions, like what's the ifs? Right, what is the if? Because that's underlined what you're asking.

I think that that's all the stuff that we're going to get to, which is, what's the market gap? Is there a market failure? Is there a reason to think that the market can't do this on their own? Does the market need a set of standards or requirements that might create an opportunity where one doesn't seem to exist right now? One of the things that we certainly heard was, that to use the term that people were using at the hearing, this isn't one and done, meaning that we could look out and just find that organization that has got the exact directory that we want. Whether it's CAQH or SureScripts or NPI or the upcoming NOR, there it is, and now let's just use it.

It was very clear that that's not the case and we shouldn't expect it to be. Because as we think about that, that I think was a very useful watch phrase was that directories are bi-products of business processes. We're talking about a different business process here. So not surprised that the directory, no directory is quite fully developed to be aligned complete with what we're talking about here.

So just quickly, I know we're getting short on time, there's always danger, and it was certainly reflected within our workgroups, of trying to put down any kind of picture of anything, because the world is very complicated, it is very complicated. For any particular picture you try to put up, there are ten examples of a way that technology or businesses are instantiated in the market that differ from what you're putting up there. So it is with that very great caution that I put this up. I do think that on net, it helps to communicate, but I want all of you to decide for me here at the end of the day.

What we tried to depict is, what is, got into just a little bit of, how do we think about directed exchange in that transaction and where might provider directories enter that chain of events and provide some value? Where are the complexities as we think about the scoping and where we might want to focus here?

We've got on the left-hand side, and this a particular example of clinical entity-to-clinical entity, and it's primary care physicians and specialists or primary care at the hospital. It says EHR, so I'm using clinical entities right now, but it could certainly be public health or a lab or what have you. So you've got a sender on one side and you've got a receiver on another side. This is directed exchange, meaning that it is known, I am sending it one way. I am a sender, I know who I want to send it to, and I am sending it specifically to that person. So it's not a query type of system, there's no repository ... I am pushing something in that directed exchange, NHIN Direct kind of user story mode.

You can imagine that who we are describing. So we're going through an organization EHR, which is really the repository, to use Jim's word, that's where the patient records are, and that's where the information that I'm trying to convey is coming from that system. I am a user who has access granted to me by that organization to do certain things with that information. That's how I interface with the technology world here.

Then arguably, this is where we start to get into waiving of hands, and I'm using some of the terms from NHIN Direct right now. There is an organization EHR that then would convey information under certain type of authentication to what we might think of a HISP, and I put that in quotes. Because again, I would certainly first, I'll also apologize for not being as far along as we'd like to be in defining some of these key terms. So we throw around a lot of different terms for what intermediary gateway, HISP. HISP strikes me as being a pretty word in a way, because it builds on an Internet service provider, and you could think of a health Internet service provider being one layer on top of that.

Let's just walk through this quickly. I have to have some way for my EHR to get onto the network and to communicate with the network. Then on the receiving end, they have to have some way of being connected with the network and communicating with the network. It goes to the organization EHR and then gets delivered to the user.

What are the variations out in the market? One variation would be for example, that it's clinical entity-to-clinical entity. So I'm at Elliot Hospital in New Hampshire and I'm referring a patient to Dartmouth-Hitchcock. I would need in that case, I am the HISP, and I'm the organization EHR. So I actually wouldn't need that middle step of authentication to send, because I am both, the HISP, so that's integrated in one. The EHR, the entity, is kind of the HISP. On the other side, the same thing. So I don't need anything between the EHR and my HISP as it were, I just need that in the center to say, how do I authenticate and send the message from Exeter to the Epic system at Dartmouth.

What's the other end? The other end of the spectrum might be that I'm on eClinicalWorks on both ends let's say, just to broaden our EHRs. So I'm on eClinicalWorks on both ends, where in that case, there are two HISPs. There's actually just one HISP in eClinicalWorks. I'm an eClinicalWorks user on one side, I'm

sending it to another entity, another organization entity on the other side, but I don't need that middle step of authenticating. Because there's just a single, those HISPs actually merged now in the technology and organization that is playing that role.

So there's every combination you can think of out there in the market. But the reason for putting this up is first off to just recognize that in principles, directories can play a role facilitating in almost any step of the transaction. As you think about the users all the way on this end to the receiver, to the users all the way on this end. In principle, they certainly can play a role and they do, but in practice, complexity starts to rise dramatically as you try to encompass more information about end points and users into any kind of centrally orchestrated approach.

So as we think about entities, you can imagine in this picture saying, the HISP or the entity, we might be able to get our arms around that and that could be very useful. As we start to say we want to have more and more information about what's going on in those organizations, there may be greater value and a greater opportunity to start to automate workflow, because at the end of the day that's all this is about. Because this can happen without directories, it just means you're doing more manually. You can start to automate more of the local workflow, but that means that you've placed a much higher demand on the system to have that level of detailed information and to have it be accurate and reliable and timely, so that it can respond to the workflow needs.

As we think about the scoping, that's really a consideration here of starting in the middle from entity level, and really how far out do we go, and what are the issues that start to arise there. Latanya?

Latanya Sweeney – Laboratory for International Data Privacy – Director
Yes. The thing about this is, so having the provider directory is central. Doing it this way, you're ruling out lots of other ways to do things. The beautiful thing about the Internet was all I had to do is find the IP protocol and give a DNS and things could work.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
Yes.

Latanya Sweeney – Laboratory for International Data Privacy – Director
It's that kind of lightweight thing that would be ideal. For example, the system that Jim and them put together, if you bill, if the manufacturers played this game, they can't play his game. There's at least 12 other employed people, but on the other hand, if you just provided the generic provider, then everybody could play the game. This is kind of over fitting to NHIN Direct.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
Oh, yes, so let me just, so I think that one of the things that you're pointing out is the danger of putting up a particular two-dimensional representation of anything. Because when you say that this way is the wrong way or is a particular, we don't have a way yet. Certainly, no one in the workgroup would say that we have a way. All I'm trying to do is characterize what systems look like today and what the problems are that we might encounter.

Latanya Sweeney – Laboratory for International Data Privacy – Director
Right, but you can imagine, you could have drawn it where you could have the same conversation. But by drawing it this way, it fixates peoples view that this is how the data would have to be exchanged. You went into great detail that there might be this HISP and so forth, and if I have that, then it begins to rule out lots of other paradigms that are already out there with a lot of companies who are willing to put money on the table, who have put money on the table, and this just sort of rules them out.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
No, I don't think it does—

Latanya Sweeney – Laboratory for International Data Privacy – Director
It's not even necessary from providing a provider directory.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
I don't think it does because the HISP here, and again, I recognize the danger of putting this stuff up like this, is that that's really a concept. It's not a thing.

Latanya Sweeney – Laboratory for International Data Privacy – Director
I'm sure. But there are many designs that don't require that concept to be a part of it.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
Okay, fair enough. We're certainly open to, if I have suggested that we are wed into a particular paradigm, we're absolutely not.

Latanya Sweeney – Laboratory for International Data Privacy – Director
I'm glad to hear it.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
But actually, I'll want to talk to you offline about that and perhaps have you come and speak to the workgroup about it, absolutely.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
I think we only have about five minutes left. You may want to show your last slide and let us know how we can help you at this stage.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
Sure. On the last slide here, this is not a slide that we wanted to go through in any great detail, but just to convey to the committee, how we're starting to think about the next steps. Which is to say, if we're just thinking about an entity-level directory, there are a ton of questions that we have to start asking related to what type of functionality, what are the policy levers, and what kind of standards might we be thinking about as we think about that.

This is really just an initial list of the questions. Deven has already added a couple that we need to add here in thinking about this. It's not meant to be complete, but it is meant to be highly representative of the type of detailed level of conversation I think that we're going to be having over the next couple of months. In terms of the committee, would just love any feedback on the principles, and if that feels like a good grounding, and if this feels like the right approach in terms of the way we're incrementally looking at it, and with this as an initial set of questions.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
You'll be expected to come back in November and December with what?

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
With focusing first on entity-level directories and a set of recommendations related to entity-level directories. Then in December with something more along the lines of what we'll call in quotes, the clinician level. That's a little bit more vague right now in terms of what that exactly might look like, but that's the overall plan here. There's a lot of work to do between now and then, but that's our current plan and we're trying to set aggressive timelines for ourselves.

In part because we're getting the feedback at the hearing that we had, we had a state and regional framing panel. Certainly, a number of these programs, whether we've got $600 million out there in HIE funds, as well as a lot of money on the Beacon grants, just to name two, as well as Medicaid. All of them looking for provider directory solutions. There's a certain sense of urgency that's coming up from the bottom saying that we need an approach before we start investing these dollars. We're going to invest

these dollars anyway and we could be worse off a year from now for not having at least come up with some type of recommendations.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Any final comments? Yes, we'll go with Art?

Art Davidson – Public Health Informatics at Denver Public Health – Director
With regard to your question about if it is the right principles? In general, I think these are the right principles, but the way that they're described here really is in support of HIE. I'm not sure whether all of these principles really apply to the provider directory. It starts out the considerate and the development of provider directory policy recommendations.

Deven brought up the issue of, so who gets access to this? We start out with openness and transparency, but then the next thing is, I think back to how I solved clinical problems with patients. Patient's being seen by another physician, I ask them to fill out a release of information form, it goes to the front desk, someone looks up in the phone book or online, the address of the doctor, and I get the information on a release of information. That process, there's a phone book and it's open, and anybody can use the phone book.

So I'm not sure, when it says about collection use and disclosure limitation, whether that really applies to the directory or to the active exchange using the directory. That's to me a little bit confusing. So I'm just trying to comment on that, I don't know the right answer on how to fix that right now, Micky, but that's just my impression from reading the description of these principles.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
Yes. My quick answer is that for example, openness and transparency of the idea is that the openness and transparency is with regard to those whose information is being put in the directory and being open and transparent about how their information is going to be used. So I don't know if that answers your question.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Judy, did you have one?

Judy Faulkner – Epic Systems – Founder
Yes, it's a very quick one. By the way, I really liked your .... I don't know if you have taken a look at those that are already existing out there with the directory exchange. Some of the vendors that you had mentioned, and put some technical people on it to see technically what do they have to do to get it done. I think if you haven't, that would be a really good thing to do. Because then you'll just know that, here's where they're all the same, here's where they're different, here's how we can map, and that might really jump start you.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
Yes, I completely agree.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Very good, thank you very much, Micky.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
David?

David Lansky – Pacific Business Group on Health – President & CEO
Micky, one more thought I just wanted to relay. Looking at this list of next steps and thinking back to your opening comments about the hearing and the business requirements and the business process driving the provider directories. I think we have a warrior or challenge that we, it's the only business process that

this set of recommendations addresses as meaningful use stage one, two, or three. It's disconnected from all the other, as Judy is suggesting, other directory functions that are out there. That would not be good.

On the other hand, they're all obviously chugging along serving frequent business requirements. I was thinking maybe we should add to this slide and the concept behind it, kind of the business analysis step, which is to continue to work on the harmonization of the business requirements that come out of the meaningful use process with the other business requirements that are already driving directory services, so that we have a dialogue going on with that community.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
Yes, okay.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Thanks, Micky, great. Our next topic will be privacy and security, from the Privacy and Security Tiger Team related to transparency, and that's Deven McGraw and Paul Egerman.

Deven McGraw – Center for Democracy & Technology – Director
So we took a small vacation, but we're back. I thought for a second about saying, Paul and I could probably just stay at the ... but then again, how could we kick each other under the table if we weren't sitting here. We've agreed to only take up a half an hour, and so we're going to be light and nimble in our presentation here. We really have, here are the tiger team members for those of you who forget who we are.

So I want to say, we have two primary goals with this presentation, probably most importantly to deliver our next set of recommendations, which are on openness and transparency, but as important is to layout our plan for moving forward. To remind folks that what we're doing here is not to cherry pick issues or just sort of pick them out of the sky, but to instead create a comprehensive privacy and security policy framework that can govern health information exchange going forward.

In hence the reason why we've got this lovely document that has these nice circles representing the overarching nationwide data sharing principles, as well as the technology principles that were adopted by the Standards Committee. Then with respect to each of the policy principles, there's a deeper articulation of policy requirements. What we did after our August recommendations was to take this chart and fill it in with what we're already done. But you'll see that notwithstanding that we filled in some big chunks. We've still got some big gaping holes. Our endeavor is to start filling those holes overtime.

We're still called the tiger team, but we're trying to work on a much more manageable schedule so that we don't lose any more members. But inevitably, this is the document that we would just be continuing to work on, on a piece-by-piece basis. Making it available to the public so they can see and put in a framework, and see what we're doing, and see how the issues interrelate to one another. So that's what we're doing here.

Today's update is of course, is an initial set of recommendations on the principle of openness and transparency. Our goal today is to get endorsement of the recommendations so we can begin to fill that box in on the chart. Again, this is not just an issue of paper; although, we did give you a lot of paper. This is not just an issue of paper and diagrams and semantics, but a real, just demonstrating those to the Policy Committee, as well as to the general public that our overarching goal here is to create a comprehensive framework. You have to do that piece-by-piece and that's what we're doing, but ultimately our goal is to have this completely filled out and be a working and useful document for folks going forward.

With respect to the recommendations that we're presenting today, we did give you again, we might call ourselves, not the paper tiger team, but we do have a tendency to give people a lot of paper. But we did

set our recommendations out in some detail in a document that you did receive in advance of the Policy Committee meeting. Because we don't have as much time to do our verbal presentation, we're going to hit the high points in our slides today.

Paul Egerman – Software Entrepreneur
I'm going to quickly walk you through some of the core values that we have. The first one is, this is just repeating what we presented to you before last August. The first one is very important, and it's patients should not be surprised to learn what happens to their health information. This is a very important core value.

The second value that we have is that the provider/patient relationship is the foundation for trust in health information exchange. A foundation for trust in a lot of other things also, but certainly in health information exchange that provider/patient relationship is the foundation.

The third one is, it sort of grows out of it in the previous series, the providers themselves are responsible for ensuring the privacy and security of the patient information. It does say however, they may delegate functions to business associates if done in a trustworthy manner.

Deven McGraw – Center for Democracy & Technology – Director
Let's work on our slide.

Paul Egerman – Software Entrepreneur
Well, that was actually put there on purpose, because the whole thing was about delegation. This shows how important it is to delegate, like the PowerPoint presentation, in a trustworthy manner. These are basically the core values.

We did end up with a new value that is very interesting. The first part says, transparency about information exchange is a necessary component of establishing creditability with patients. We want to be clear, we're saying it's a necessary component, we're not saying it's a sufficient component. There are other things you need to establish creditability. But certainly transparency and openness, so that people know what's going on, is one, a necessary component that we need to establish creditability.

The second sentence is also as important too, we want to in achieving greater openness and transparency, we need to balance the need to give patients complete information. We want to give people complete information on how their information is shared, while at the same time provide information reform that is manageable for patients to read and understand. We're acknowledging that there's a fundamental challenge in that process.

Deven McGraw – Center for Democracy & Technology – Director
Right. The real challenge here in transparency is how can you give patients that complete level of transparency without creating a notice that's completely unmanageable for patients? They can't read it. It's too long. They can't understand it. It's just a piece of paper that's in piles of paper that they collect, but also not creating an undue burden on providers. That's the challenge that we chose to take on.

Overwhelmingly, the solution with respect to at least, again, this transparency piece is to do so in a layered way. We apply that layered approach in three different contexts, one is to talk a bit about the HIPAA notice of privacy practices, which is already required for any provider who's covered by HIPAA; which is largely the universe of providers that we're talking about for the meaningful use program.

We've also applied it to what we're calling here for shorthand purposes, indirect exchange. When we use that term what we mean is, the type of exchange that triggers meaningful consent per our August recommendations. So exchange through a vehicle that triggers consent per our previous recommendations for the sake of distinguishing it between directed exchanged, which we said should not require additional consent beyond what already may be the case in current law, whether it's at the federal

or state level. If it's not directed, then it could be called indirect. That's a shorthand way of referring to exchange that triggers consent per our previous recommendations.

Then the other context where we have applied a layered approach is with respect to organized healthcare arrangements and other integrated delivery networks, which we just generically referred to in the recommendations as OHCAs, because it's just easier to refer to them that way. But again, as you'll recall in our August recommendations we said, we made a clear distinction between the type of arrangements of networks that would trigger consent, like a centralized HIO for example; is very different from an organized healthcare arrangement for which it's a vehicle that's already recognized in HIPAA, and involves the sharing of a record by multiple entities together. HIPAA already has standards for what it takes to become an OHCA.

We have some recommendations that get to the issue of transparency for OHCA, in part because certainly these arrangements are different for patients for many of them. We already said in our August recommendations, we're not going to require patients necessarily to meaningfully consent to having their information be part of these arrangements, but certainly under our core values of patients not being surprised about how their information is shared. Certainly there needs to be transparency about these arrangements to patients.

We applied our tiered layered approach to those three contexts as well. So I'll talk about the specific recommendations we have with respect to the HIPAA notice of privacy practices. Then we have distinct recommendations on layered approaches for both indirect exchange and OHCA type arrangements, which Paul will handle. Then some additional recommendations for the role that ONC can play in helping to educate patients about these arrangements.

So again, this is a briefer statement than what's in the actual document that we provided to you. But we actually recommend that the HIPAA notice of privacy practices be provided in a layered way. The notices already were required, but right now it's just one notice. We think it could be more effective if it was done in a layered way. So a short summary of sharing policies and activities with an opportunity for patients to get a much more detailed notice, which describes the sharing practices in more detail.

It should be plain English and in an appropriate reading level. We use the term plain English here, but we also have some recommendations in the document about language issues. This is already something that providers need to accommodate. We're not trying to change that and say everybody has to do an English notice. This is summary, but it should be understandable I think is the key term here. That encompasses also an appropriate reading level. Sometimes this stuff is all written in legalese for whatever reason and that's not helpful to patients.

It should cover current and anticipated exchange actual activities. Not just, the law allows us to disclose it for this purpose, because that doesn't say very much to patients about what's actually happening with their data.

Paul Egerman – Software Entrepreneur

To walk you through the other two cases, and it does mention there's three. When there is indirect exchange. Again, that's the expression we're using for those circumstances that trigger consents that we discussed in our previous recommendation. The first part, where we're saying about the notice, is it should not be buried in the NPP, the notice of privacy practice, but easily distinguishable. I want to emphasize that, if I can get my laser pointer thing to work here, there it is. So that was a very effective way to use the laser pointer, easily distinguishable.

The issue here is, and it's like Deven started talking about having a lot of paper, this is not something that should be buried in front of a privacy notice that's already difficult for most patients to deal with. This has to be somehow distinguishable. That we did say separate, because we didn't necessarily want to say to people they have to have something completely different, but it has to be distinguishable. That might

mean it's got big bold red letters or something, but it's somehow distinguished from the rest of the notice. So that's really important.

The second important concept here is that it's layered. In other words, that Deven just mentioned, so there's a brief summary. This is a brief thing that's in bold or somehow distinguished. Basically, the brief summary provides information about how more detailed information can be obtained. The fundamental idea is the detailed information, the transparency requirement is meant that the detailed information is available. Because there may be people like privacy advocates or consumer advocates that will take the time and read through all the detail, but we didn't want to force the patients, every patient, to have to read through all of that stuff. Of course, it has to be provided in advance. So that's the second case.

The third case is with respect to these OHCAs. As you may remember, OHCA is part of the healthcare alphabet soup description of all the different entities that exist. That sometimes you see a healthcare provider, even if you've only seen one organization, you may later, you get five different bills. So it's like, who are all these different entities? What happens is, there's a lot of questions when we presented last August about what happens in the case where a community physician has his or her medical record hosted by a large integrated healthcare system in the city. We said, well that's a transparency issue. So that's what this is, it wasn't a consent issue, it's a transparency issue. So this recommendation relates to that.

So with respect to OHCA, there should be some similar summary information. In the example I just gave, it could be something like, your physician is a member of ABC health system, and if you want to find out more about it, here is the information. The patient should have the ability to find out what the more detailed information is, which would talk to the information about who has access to that record.

We also made a recommendation about public education, because on the one hand we're saying the providers have to be responsible for all this. They have to provide the notice. They have to provide the information, but we want to make it administratively easier, but we think also that ONC has responsibilities to health. We're saying that ONC should use its funding capabilities that's leveraged to make sure that HIO organizations and regional extensions that is developed and implement public education plans, and that that's important.

Then we also produced a number of sample notices. This is one in the PowerPoint. There's a few more in your paperwork. You see this is a sample notice. It's actually a little bit long, but it says, we sent an electronic copy of your medical record to the state health information organization, normally that would be named NWHIN, whatever it is, which makes your data available to other healthcare professionals, if assuming that's what they do.

You see the second sentence, we also used a gateway for electronics submission of prescriptions, which keeps a copy of your medication profile. We put that second sentence in to make the point that these recommendations do not apply only to these HIE organizations. There are some vendors that do things like E-Prescription Gateways that this recommendation on transparency maybe applied to.

Then you see and you're saying, if you want to learn more, if you can request the details, which could be in the form of a booklet or something, but we also said it could be appointed to a Website. So again, the Website might be provided by the provider organization, but it could be provided by the HIE organization or by the vendor. So that you can point them to some other Websites that they would provide to a system providers.

So those are as short as we could our recommendations, and we're asking for your approval as part of this, basically, the privacy framework, which you'll get a final opportunity to approve. Before we open it to discussion, I also wanted to comment on the previous discussion, that Micky did a terrific job. He mentioned basically provider authentication. He said, the tiger team is actually going to be addressing provider authentication next. After that, we're going to be addressing some patient access issues, but

we're doing provider authentication next. In the HIT Policy Committee log, there is an entry being, either it's already there or it will there, where we're asking for some feedback on that issue.

Having said all that—

Deven McGraw – Center for Democracy & Technology – Director
Can I just add one other thing, Paul? I want to make sure people understand because we did get some questions about this, that with respect to the notice and public education about trigger arrangements or indirect exchange arrangements, remember that we had a whole set of recommendations in our August letter, which you all already approved about meaningful consent. It was not at all reduced to a single notice.

So this discussion here today with respect to indirect exchange though trigger HIOs was to make clear that, number one, notice about this shouldn't be buried in the HIPAA notice and should be done in a layered way. But this should not be interpreted to supersede or undermine the very clear recommendations that have already been adopted by this committee in August that make very clear that full and open transparency is really what's required to educate the public on those types of exchange arrangements that deviate from what patients expect.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Great, thank you very much. We have Jim, Neil, Art, Latanya, and then Larry.

Jim Borland – SSA – Special Advisor for Health IT, Office of the Commissioner
Deven, let me just throw this out for maybe future consideration. But I think it's very relevant to this part of the discussion, is that the workgroup whether you have looked at this or not, consider looking at the issue of electronic notice. Because it's something that the original HIPAA legislation did not anticipate. And for those of us who are still dealing with consent, with authorization kinds of issues, an explicit recommendation by the workgroup to allow electronic consent authorization notice, I think would send a signal to both the privacy security community, as well as to the vendor community, explicitly allow it rather than imply it.

Deven McGraw – Center for Democracy & Technology – Director
I think that's a good point. I think that's something that we'd have to dig into a bit, but given that we're moving into an electronic world, completely appropriate don't you think, Paul?

Paul Egerman – Software Entrepreneur
Absolutely. We're sort of taken a step towards that by saying you can have the details in a Website. But an excellent point, you're 100% right.

Neil Calman – Institute for Family Health – President & Cofounder
I think this is really, really important stuff. The thing that I keep wondering about is, and this example notice sort of highlights it perfectly. So it says that we're going to make your data available to other healthcare professionals, but it doesn't say what they're going to do with the data. It says we're going to use it for a gateway for your prescriptions, and that they're going to keep a copy of your medication profile, but it doesn't say what they're allowed to do with your medication profile.

To me, that kind of like completely negates the whole value of it. Like what good is it to say, we're passing it to step one, but after that, sort of like there's nothing, we really can't tell you what's going to happen with it. I guess so that we're not faking this thing, what are we really saying to people?

I guess the other thing is that as those networks change of who we're doing this with, I know we talked about this in terms of like requirements that sort of re-notice people about changes and stuff like that. But in reality, I think we're just piling burdens of stuff on it. Where at the very beginning of this networking

thing that's going to grow like a spider. It's going to be impossible to try to keep people informed as to all of the ends of this web.

So what are we really trying to accomplish here? I guess the alternative thought would be, should we just send a signal out there to everybody about what it is, the big picture looks like, and try to inform people about what this big picture looks like? In fact, not try to do this little piece of it.

Paul Egerman – Software Entrepreneur
Those are all great comments, Neil. In some sense you're right. The challenge is if you're going to do any kind of a summary notice, what's going to be in the summary and what's going to be in detail notice. Then you say, what are we trying to accomplish? What we're trying to accomplish is this concept of transparency. We want all the information to be out there, that's what we want to try to accomplish. We think that's what's going to build creditability. But we also think that not everybody wants to read all of that stuff. So that's fundamentally the challenge.

The analogy that, maybe not a good analogy, I sometimes use if you look at like the FTC where it requires publicly-owned corporations to produce an awful lot of information, but not everybody really goes through all that detail. You sort of rely on somebody else to go through that detail and tell you something about it. So the idea is, what we're trying to accomplish is to have the information out there, to have it developed out there for privacy advocates. What we didn't do is we didn't say what the boundary is between what's in the summary and what's in the detail, and that's up to the providers to choose.

Deven McGraw – Center for Democracy & Technology – Director
So here's another way to answer the question, which is to say that we think the notice piece of this from a transparency standpoint is important, but it is in no way sufficient. It's the reason why you don't try to load on everything that you care about in privacy and security into notice and consent. Because the reality is, that the way that that entity handles the information once it goes there and what the gateway does is very important to patients, but we should not leave it to just a transparency regime to resolve. There should be some very clear standards that they have to meet and be held accountable to with respect to how they share your data.

But we don't want to also say that there isn't a value to trying to make people aware of what's happening. So I don't know that we want to say, we're just going to eliminate this notice whatsoever, because people do see their physicians and their care providers as sort of their first line. As we said in the core values, that's sort of where the trust relationship is. But the recommendations fully recognize or maybe not as fully as they could, but our goal was to acknowledge that that's in no way sufficient. No way is it sufficient from a protective standpoint. We called on ONC and the recs to do public education campaigns, and the funded HIOs from ONC should be doing education campaigns.

Our goal here is a much more informed and engaged patient community, but you're not going to just get there on notice alone, but you don't want to leave that out. I still think there's a value. If you all think that there isn't one at all, we can certainly address and talk about that. But I want to make sure that we did not put this forward to the tiger team to say, "Okay, this should do it, double layer notice, closed book, goodbye."

Neil Calman – Institute for Family Health – President & Cofounder
I just want to make it clear, I wasn't suggesting not to do it. I was suggesting that there might be another sentence that needs to be put in there, which says that beyond what we're telling you here.

Deven McGraw – Center for Democracy & Technology – Director
Right.

Neil Calman – Institute for Family Health – President & Cofounder

Yes. There's a lot of other things that are going to happen with your data and here's where you go to find that out.

Deven McGraw – Center for Democracy & Technology – Director
That's fair.

Neil Calman – Institute for Family Health – President & Cofounder
Because it did suggest that you're sending it down to two places that are basically dead ends. I guess my suggestion is, that's really dishonest. They're not dead ends, and people need to know that they're not dead ends, and here's where you can go to find out what the other pieces are maybe is a way to compromise that.

Deven McGraw – Center for Democracy & Technology – Director
Okay, yes, that's fair.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
I realize that probably ... of scheduling privacy for a half an hour.

Deven McGraw – Center for Democracy & Technology – Director
Talk faster everybody.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Yes, so can we keep it really short. Somebody else had, Art, Latanya, Larry, and then Gayle.

Art Davidson – Public Health Informatics at Denver Public Health – Director
Thank you for the presentation. I did agree to all this recommendation and have been trying to convince all my HIE colleagues that we don't need to worry about certain things that they keep bringing back. The framework document that you have here has under the individual choice, an item listed under the policy column that says, standardize opt in or opt out, question mark. What does that mean?

Deven McGraw – Center for Democracy & Technology – Director
Which bullet is that?

Art Davidson – Public Health Informatics at Denver Public Health – Director
It's on page 7, and it's the lowest bullet under the individual choice in the policy column.

Deven McGraw – Center for Democracy & Technology – Director
Yes, okay. It's a note about whether we need to do further work on this. That may have been a vestige of an earlier diagram before we resolved the issue through the Policy Committee, that we would adopt a recommendation on meaningful consent, which includes before it leaves the providers control. I think this is old. I certainly don't think we have, we really don't want to take that up again.

Art Davidson – Public Health Informatics at Denver Public Health – Director
It can be fixed, okay, thank you.

Paul Egerman – Software Entrepreneur
Although, it was a fun discussion.

Latanya Sweeney – Laboratory for International Data Privacy – Director
So I give you many compliments for the work that you're doing and for the transparency focus, and I think the core values are excellent. A couple of months ago, we did a survey to show all of the places that a fictitious Alice would go based on the NRC report that had come out pre-HIPAA. We wanted to say what does that look like now post, now that HIPAA has been out for eight years. The number of places outside of the care of the typical patient, Alice, was shocking. Almost everyone just has the same shocking.

Then the second sentence says, "Oh, but you forgot something." So this is pre-EMR adoption, so we expect another explosion. The biggest problem there is a lack of transparency.

Relying on privacy notices in the same spirit of transparency, it has a lot of flags go off. So in Internet privacy, that's pretty much how it's been. The FTC is getting ready any day now to release a document they've been working on feverishly to say that this hasn't been working for us, these privacy notices. We've tried all kinds of things. They tried color coding their privacy notice, they tried a simplification summary, they tried standardizations, not they, FTC, but meaning the industry and the consortiums that work around the industry. For the most part, it's hard, because people basically only have one choice. If I want this service, I have to click this through, through this button, and it really doesn't matter what it said. So these just add a lot of complications.

But one of the things, people who like the high-tech bill, people who are in privacy who like the high-tech bill, one of the things that he pointed to, and he said but we can do better in transparency than that, because we have these great audit requirements. On the other end, I could actually use audit as my transparency. That is if I'm the patient, I should be able to get the kind of diagram that we created for our fictitious Alice, I should be able to have a system that generates that. So I know all of the places my data went. That also helps me that if there's a breach, I know whether or not I'm likely to be at risk.

So this kind of very functional transparency, I think is far more powerful. I'm not saying that you shouldn't do notices, but notices are extremely limited. They seem like they give people choices that they don't have. It's not like I can mark out part of it, I don't want them to get that part, and I still can get care. It doesn't have that kind of agreement.

Deven McGraw – Center for Democracy & Technology – Director
Yes, I don't disagree with you at all, which is why we tried to carefully say, it's an initial set of recommendations on transparency. We actually have put off consideration of how to implement the new accounting of disclosure requirement, which is what's more enhanced than it has been. In part because there already was a request for public comment on that, that's closed, and what we do on the tiger team to have maximum impact. If there's already an pending rule going through the pipeline, we might come up with recommendations that are either not informed by the rule or are sort of off timing.

But yes, I completely agree. With this, I don't know how many more times I can say it, not sufficient, not sufficient, I totally agree.

Latanya Sweeney – Laboratory for International Data Privacy – Director
Right, but I will also have you reconsider, instead of waiting on the other one, because your scope is different. For all the reasons that you could ignore the HIPAA rules for some of this other stuff, you should just ignore it and come out with what you think is the right thing.

Deven McGraw – Center for Democracy & Technology – Director
That's fair, okay.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Very short, Larry, and then Gayle, you'll have the most prize, last word.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
I really liked Latanya's suggestion that using audit trails as a tool to help people actually know what's happening, so we get out of the speculative world and into what's really there. I think with all the experience with the financial privacy statements that we get, and I don't know, I just shred them. Anyway, but I'm wondering if, so Neil raised the question, we don't know what happens when you're finished. I hand it off to this other organization and what happens then?

I think it might actually be helpful if in your examples, you try to scope the intent. So I'm providing this information to the state health information organization, because I want to make it available to other providers who will have a care relationship with you in the future or have had one in the past; or we're making this med profile available to facilitate med reconciliation, both in this office and as you go to other providers. So that there's an educational piece in the notice that kind of explains to people, "Well, why are you doing this?"

Deven McGraw – Center for Democracy & Technology – Director
Right, I mean it does. But you could immediately see how that would be limiting, because it's so broad and general, and doesn't really say— We're back always with the challenge of wanting to provide people with something that tells them more than what they're getting today, but yet understanding that the devil is in the details. That's a really hard thing to do in a very transparent and good way.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
Yes, so I think I really like the notion that says, "And you have access to an audit trail that will show the chain of where your information went."

Deven McGraw – Center for Democracy & Technology – Director
I'd like that too, Larry.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Alright, Gayle.

Gayle Harrell – Florida – Former State Legislator
Thank you for the last word. First of all I think we need to understand that all this is happening within the aspect of education of the public. I think it needs more than just this simple notice. I like the audit trail. I like there's a lot of things we can add to this notice that will make it even better, but it has to be in concert with the education component. It also has to be in concert with a strong governance mechanism that are going to make sure that the entities out there that are going to be holding that information or at least transiting that information have responsibility.

That they have transparency requirements as well, so this is not in a vacuum. I think that is part of what we need to understand and we also need to make sure the public understands that there's standards, there's governance, and there's education that goes along with it. I really like the audit trail aspect. Also Neil's component that says we need to make sure that people understand within this simple thing that this is not just the people who are going to have it, that there's going to be the potential for other people to have it.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Yes, one really quick thing.

Latanya Sweeney – Laboratory for International Data Privacy – Director
I'm just agreeing with the others who have been speaking, because I think short is really going to be much more beneficial than long. If we add all this education, by the way, a typical person doesn't know what meds reconciliation means. So we're going to have to educate to educate. I think we only need to do when it's something like, and you're data will be sold or you're data will be shared with places you don't—so it should be for the stuff that the people think might be a danger. I would drop all the education.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Do you need us to approve this?

Deven McGraw – Center for Democracy & Technology – Director

Yes. So what I'll ask for, because we've got a lot of feedback on some additional work to do. In order to put these in an initial, a not sufficient entry into the transparency box, but a starter on notice issues. We would like to move forward, but taking into consideration the comments that were received here.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Paul, so based on those comments, I think we'll say this is—

Deven McGraw – Center for Democracy & Technology – Director
Okay, no.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
—not only necessary and not sufficient, it's probably necessary and inadequate. But if we can live with that, then—

Neil Calman – Institute for Family Health – President & Cofounder
If we're going to say yay or nay or this, can I just add really, really quick. You say, including a list of all participants.

Deven McGraw – Center for Democracy & Technology – Director
That would be in the longer notice, not the short one. I mean anybody—

Neil Calman – Institute for Family Health – President & Cofounder
That would be all potential participants or the all actual participants?

Deven McGraw – Center for Democracy & Technology – Director
This is with respect to an OHCA, right?

Paul Egerman – Software Entrepreneur
It's not naming individual. It would say like clinicians who practice at ... Hospital.

Neil Calman – Institute for Family Health – President & Cofounder
That could be a really, really long list.

Paul Egerman – Software Entrepreneur
Yes, I know noticed something, it would be a long if you had to say each person, but you could just provide a description, the types of people ....

Neil Calman – Institute for Family Health – President & Cofounder
So all potential participants.

Latanya Sweeney – Laboratory for International Data Privacy – Director
But business associates, even if you just list categorically, like you have to include your trash people who do ....

Paul Egerman – Software Entrepreneur
No, no, no, no.

Deven McGraw – Center for Democracy & Technology – Director
No, these are participants in an organized healthcare arrangement. So you're right, we're not talking about every ... all the people who get Alice's record from your spiral diagram, which I've seen. But just again, if it's the Mayo Clinic OHCA, who's included? The practice down in Florida, the practice in Minnesota.

Neil Calman – Institute for Family Health – President & Cofounder

At that gross level, then the practice down in Minnesota or each individual clinician and nurse and move on.

M
These are the people that ....

Neil Calman – Institute for Family Health – President & Cofounder
Right.

Latanya Sweeney – Laboratory for International Data Privacy – Director
....

Paul Egerman – Software Entrepreneur
The issue is that the patient shouldn't be surprised. So as they go from the cardiologist to being seen at the hospital, and their surprised that the hospital has access to their records.

Neil Calman – Institute for Family Health – President & Cofounder
I promised Paul it would short. That's just a worrisome statement there that we would want to clarify, but with that said, I'm good.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
I think it may be in our committee members minds whether we think we've got close enough. They can edit and take into account the comments or would we rather them come back as a tack on to a future meeting, so that's up to you to decide. The motion that would be on the table if somebody would make it, would be—

Deven McGraw – Center for Democracy & Technology – Director
So here's another possible way to cut this, which is since we have already characterized this as an initial set of recommendations on transparency that are not sufficient is for us to take all of these into consideration where we continue to build the box on transparency. That also would include some of these other issues that we're taking.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
I think that would be a better approach ....

Deven McGraw – Center for Democracy & Technology – Director
In the same way that we did it with you all this summer, which is to start feeding your our thinking and getting feedback orally on. But as Paul actually said in the presentation that there's going to be a wrap up to all of this at some point. We've gotten some very helpful feedback today and it's not at all unlike the very discussions we had in the tiger team where we were weighing, "We've got to tell people. Well, it's too much information."

But also it was a very good discussion we've had here about the fact that notice is really not the ballgame here, there's so many other things that we need to do from an openness and transparency standpoint, that we keep that discussion open and not close it until we've flushed out some of the other pieces of it.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Yes, because I think there's only so many times you can come to us and say, this is necessary, but inadequate, but trust me, when we put it all together it will work.

Deven McGraw – Center for Democracy & Technology – Director
We're getting to the adequate, right?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

So that would be very helpful.

Deven McGraw – Center for Democracy & Technology – Director
Okay.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
This was a really good discussion as it always is, so thank you very much. Thanks, Deven and Paul. Then we'll go to our final topic, which is an update from the governance workgroup and John Lumpkin is here to update us.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Good afternoon. I guess you know who I am anyway, because it won't stay up. It is wilted in this afternoon. I'm going to talk a little bit about the workgroup of the Policy Committee. The last time I presented it, I wasn't here in person. I'm sure they had my card standing up at that point, so you at least knew where the sound was coming from. The purpose of that was to talk about the charge and the initial discussion to the committee.

This time we've gone through the process of thinking, what does governance look like? What are the things that are covered by governance? Then our intent was to come back at the next meeting with the answer, assuming that you think that we roughly have an adequate, sufficient, or whatever definition of the what to address the who and how that governance process would work. We particularly did not want to go directly to the who, because we think that doing a very methodical approach will better enable us to identify what governance ought to look like.

The members of our committee, to remind you of that, are on this slide, and they're also in your hand out. So if you don't want to do speed reading and still want to get out today, I'm just going to pass over that. Today, I'm going to talk about the workgroup charge, the framing for the nationwide health information network governance. If I can have your forbearance, since I don't want to keep on putting the asterisks, I'm just going to call it the HIN, and we'll figure out what we're going to call it later. The findings from our hearing analysis and some preliminary recommendations.

Some may ask the question, why address governance now? The simple answer is, because high tech requires it, but I think that there are other reasons. First of all, governance is essential to make decisions needed to accomplish the health information technology agenda and the goals of high tech. It's necessary for the existing limited production exchange to expand and grow beyond those entities under federal context, grant, or a corroborative agreement.

So we've got some exchange going on at a national basis within the health information network. There's an exchange going on in other places. But if we want to see that expanded into a network that becomes more rationalized, then we need to have some discussion and decision on governance.

It's necessary in order to validate and assure that conditions for trust in a nationwide interoperability exists. You're going to hear that term from me frequently, trust and interoperability is our goals. Also recognizing that we're beginning to see other governance structures come into place. For instance, states are starting to pass legislation, such as in Minnesota, and regulations related to how governance should occur. It may not be the best thing for an interoperable system where folks who work in Kansas City have one type of governance on one side of the town and a different kind of governance on the other, because they're in two different states. We also believe it's necessary for a transparent oversight enforcement in accountability.

Let me get to the charge of the committee. Basically, we were given the charge to draft a set of recommendations on the scope and process of governance. That we are looking for the components of an engenders trust in the nationwide health information in the HIN, and it will promote and facilitate

broader participation in nationwide exchange. Recognizing again, looking at any environments, nationwide could be from one side of the town to another or from Poughkeepsie to Paducah, Kentucky.

There's a third item in our charge, which we took upon ourselves, even though it wasn't given to us, and that is to preserve space for innovation. So the key questions are, what needs to be governed in a centralized fashion and when should there be a coordination by federal government across government roles and for certain function services and so forth?

We provided a little bit of grid to show you what we're focusing in on and what we're not focusing in on. So we're looking at the processes and structures to ensure a trusted health information exchange and we're not going down into looking at the specific standard services or policies. We're looking at how they are established rather than what they are.

We're looking at examining the aspects of governance within the authority of the ONC, but we're not looking outside unless it becomes significantly obvious that these issues have to be addressed if we're going to have nationwide exchange. We're looking at identifying any mandatory or optional requirements for the preferred approach for health information exchange. Not looking for those who may not look for a less preferred approach, such as facts.

To look at our timeline, the committee started with our first hearing in late, was it just September, yes, I guess it was. We've been moving kind of fast. We're a workgroup, we're not a tiger team, but we're always ... other names, it's still a rose. We expect to come back to you on the 19th with our final recommendations.

The definition that we're using is the same one that is used throughout our work for the health information network. The HIN emphasizing it's not a centralized database, and we're looking at entities that wish to exchange information through the HIN. We recognize that this isn't evolution, so if people choose to exchange using let's say HIN Direct, that that's something that we believe ought to be covered under the governance. What would not be covered would be fax or fax lifetimes of transmissions.

Let's talk a little bit about our guidance. That we looked at and recognized the leverage existing for governance mechanisms were feasible. So the first thing we're going to do, we did, actual we did, is look at and recognized where there's existing governance and then leverage that. We wanted to as part of our process, identify and bridge the gaps in the existing governance and the mechanisms for the HIN. Then to identify those aspects of HIN governance, existing and new, where national level coordination could enhance and/or promote greater trust and interoperability of major focus. To ensure maximum flexibility for evolution and innovation and with the suggestion that we look for ways to avoid rigid rulemaking. I'll come back, as you see the last domain that we're going to talk about, it talks about how we can make sure that this is also a limiting of governance process that's committed to continuous quality improvement. Then to address barriers and promote exchange of health information through the health information network.

Let me talk a little bit about our findings. We thought that there were some key themes. Consumer privacy protections are inherent components of governance. That's a key component of building trust. Expecting that the federal government plays an important role in overall coordination. What we're looking at is a system whereby the federal government plays a key role, not all those roles are valued as a direct actor. It maybe as an actor that is delegating authority to entities to play that role. That government should be parsimonious and adaptable to future unknown needs. We don't want it carved in stone.

That there is a need for harmonization of policies to enable exchange of health information. This means that harmonization occurs both horizontally and vertically. So horizontally within the federal government and the other federal agents that are involved, as well as state governments and private entities. That common standards are needed to ensure interoperability, establish trust and security of information, and that there needs to be a validation mechanism.

We started using the term validation, because we didn't want to get specific at this particular time, whether that takes the form of accreditation or certification or some other mechanisms, but there needs to be a way to validate that those who are participating in this process meet the requirements engender trust and enable interoperability. That compliance and enforcement mechanisms are essential components of any governance mechanisms. So our balance is to improve health, while establishing trust, to ensure interoperability, while protecting innovation.

Where we did our gap analysis, we found a governance in health information technology is widely distributed, including policy development and formulation of trust framework. So we see this in different places across the nation, being done in different ways. Enforcement regimes and accountability mechanisms are also distributed, but generally in many places are lacking.

Then in the federal health information technology space, various agency jurisdiction appeared to overlap, potentially creating confusion and reducing effectiveness. That ONC is a critical intermediary, given its congressional mandates. That private sector participation and policy making takes place through consultations, federal advisory committees, congressional hearings, communication efforts. Finally, that it's unclear whether there are other sufficiently institutionalized ways for a broader scale and meaningful public engagements especially by consumers. We believe that these need to be nurtured and developed. We did not feel that it was inadequate to say, consumers wouldn't understand the technical details.

What are our recommendations? First, we come to you with a set of nine principles. These principles we believe are the foundation upon which any HIN governance mechanism should be set up. The first is transparency and openness, and you had a little bit of that discussion around that in the prior group. But we believe that it has to be a process of developing governance mechanisms, should be open and transparent, that the standards, services, and policies themselves, including privacy protection need to be clear. Not only is it important because people have a right to see what's going on, but we believe that it's even critical to engender trust that people can see how governance is set up and what it protects and how it does that sort of protection.

The second is that governance needs to be inclusive with inclusive participation in adequate representation. The process is that favorite inclusion of the diverse set of stakeholders over exclusion. That it's representative governance, including we pointed out one group again repeatedly, including consumers being engaged in part of that process.

The governance number three should focus on effectiveness and efficiency. That form should follow function and we should determine the functions, and then based upon that, the form of governance, which is why we're presenting the what to you today before we talk about the who and how. That responsiveness of the system of governance needs to be based upon understanding how the system is evolving overtime, and that one of the principles of effectiveness and efficiency is minimization. But authority as they exercise only over those issues where resolutions is necessary for the successful implementation of exchange.

Accountability is the fourth principle. We believe that the stakeholders need to be held accountable and to assure that those who are having their information exchange can have the trust to enable that to occur. That governance should be federated and be base upon evolution. Federated governance, mean that governments should not necessarily be centralized, that distribution requires careful attention to the issues of coordination at the national level, but that also governance may occur at other levels.

Evolution, that decisions about an issue should generally be made by those closest to the issue and have the greatest stake in successful resolution. Then the final component under federated governance and evolution is retention of delegated authority. That the Office of the National Coordinator may delegate that authority and remain responsible for that. And that delegation is not a permanent delegation, but should be reviewed overtime.

The sixth principle is clarity of mission and consistency of actions, that the rights, responsibilities, and obligations must be well-documented and clear to all the stakeholders. Consistency in decision making is a critical component. Decisions should always be made in the same way.

The seventh is fairness and due process. The eighth is that it's important to see that a key principle of the governance process is that it serves to promote and support innovation. The exercise that governance should be consistent with creating the conditions for innovation to flourish and reflect an awareness of the potential for unintended consequences. That within the context of supporting and promoting innovation, that in some instances such as enabling electronic health information exchange across institutional jurisdictional boundaries, standardization is necessary to enable innovation.

Finally number nine, evaluation, learning, and continuous improvement must be a component of this governance system. Therefore, that means that there needs to be metrics related to the governance process, that we should see governance as a learning system, that learns and evaluates how it's being implemented. That it continues to look and ensures that it meets the mission of ensuring trust, facilitating interoperability, and supporting innovation.

With that in mind, we have some general recommendations in areas of work. First that the Office of National Coordinator should establish a framework for governance for the health information network that reflects governance of governances. In other words, and I want to differentiate this from a network of networks, this is a governance of governances. So that as you begin to devolve governance as you see other agencies at either the federal or state level begin to play a role in governance, that someone and some entity, and we believe that's ONC, needs to think about how all of this works together. How you deal with the clashes and how do you assure coordination.

That governance of the HIN should include a core set of functions with nation-level coordination and oversight. That governance of the HIN should include opportunities for broad stakeholder input, including consumers on the strategic direction of the health information network. So the four governance functions are establish policies for privacy, establish technical requirements, establish appropriate mechanisms to assure compliance accountability enforcement, and provide oversight of the governance mechanisms.

So under establish policies and practices for the HIN, there should be a uniformed set of policies and practices that are followed as a condition of exchanging information through the HIN, and that should be reflected in technical design. Privacy, security, interoperability, eligibility criteria, by that we mean there's a process of determining who gets to play and who gets to use the monitor of participating in the HIN. First, it's the determination of eligibility, then to determine the compliance, and then finally, some understanding of how they then get validated as being a participant, that they have met the requirements.

There should be mechanisms to address gaps in policies and practices, and coordinate to assure policies and technical requirements are consistent. Then it's necessary to assure that sufficient privacy protections and safeguards are in place to facilitate and promote nationwide exchange. Exchange with interoperability and remove barriers to nationwide exchange.

The second area is to establish technical requirements. First is to adopt technical requirements through the HIN to a recognized process that coordinates and harmonizes standards, and then provides for stakeholder input, including consumers. Recognizing as an important component of that and the foundation of that, as the standards and interoperability framework that is currently used by the Office of the National Coordinator. There should be mechanisms to transition processes as technical requirements change. Authorization of technical resources for use in the HIN, such as provider directories, certificate authority registries and so forth. Then finally, necessary to assure that technical requirements are established to accomplish interoperability and policy objectives for trust, including the defined security level of assurance.

The third, compliance accountability and enforcement. This is how we assure trust and make sure that the system actually meets the expectation. To assure that eligibility criteria are satisfied, and that compliance with the conditions for trust and interoperability are met, not only initially, but ongoing, as well as clear accountability and appropriate enforcement. To do that, there needs establishment and conduct validation. As I mentioned as our catch words, we talk about how we assure that entities meet those requirements to determine eligibility and verify compliance with policy and technical requirements as a condition of exchanging information through the HIN.

To determine consequences of noncompliance with these policies, practices, and technical requirements. An individual is having their information exchanged and wants to assure that not only is it being part of the requirements, but those requirements are in fact being enforced. To provide a mechanism to address disputes, concerns, or complaints that determine how mechanisms for readdress remedies and sanctions can be applied, and consider the need for coordinated investigation and enforcement and notification of breaches.

The last area is oversight of the governance mechanisms, which is how the governance process governance itself. Oversight is necessary to assure that governance objectives are met and effective and able to adapt overtime. To track or measures certain issues or activities and support of overseeing effectiveness and efficiency of the health information network, to oversee on ongoing compliance that the mechanism is assuring and building in trust.

Then to conduct ongoing assessments, risks, and benefits for the HIN governance, including prevention of harm. Recognizing that you always have to balance how tight your privacy controls are versus the ability to actually share information. There's always a balance between risk and harm. Those change overtime as technology changes, as expectations change. So part of the oversight of the governance of mechanism is to do an ongoing assessment of that balance. To periodically evaluate the performance of overall governance mechanisms to resolve disputes regarding decision rights amongst federated governance functions.

Where do we go from here? We would like your input. Are we seeming to be moving in the right direction as defining what the what is for governance? We're beginning to explore this, and we will be coming back and looking at the who and the how. We're going to look at this in a methodical fashion. We're going to look at this based upon principles and devolution and representation. So we're going to ask the question, who is already out there doing it? Are they meeting the goals of governance for the health information network? Do they operate within the sound principles that we've addressed? Then are these mechanisms that we've already identified, are they scalable, can they take on?

The whole issue for instance of the DURSA moving from an entity that was every individual, every entity involved in DURSA was represented to a representative governance, would be one example of moving to a more scalable kind of governance structure. Then finally, after we looked at those and say, okay, what's out there, can it be scaled? If it can be scaled, where does that fill the gap? Once you have gaps that are not filled, we begin to look at the role of the ONC, and should it play that role of filling the gaps, either directly or through a delegated mechanism? If delegated, then to whom and under what structure?

That's are deliberations and we'd be happy for any insight and guidance we can get for this committee.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Good, thank you very, John. So the end point is to approve your set of recommendations. Is that the four general core recommendations? Is that the end point or just comment?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I think I'm going to learn from the last discussion, we just really want your comments, because we're going to take those and craft our recommendations that we will bring for approval at the next meeting.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Wonderful, good. Okay, Jim?

Jim Borland – SSA – Special Advisor for Health IT, Office of the Commissioner
John, first of all, I want to congratulate you and your workgroup on taking on a task that I know is not easy. I was heavily involved in the early governance structures around the NHIN. I know that there were significant gaps in those structures. So this review is very welcome.

I will ask you, I do have two questions, one is specific to your presentation and the other is more general. First of all, I believe high tech required that a governance rule be published. Can you tell us what the timeline is for that?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I can't, but I'm sure that there are people here who might be able to.

Jodi Daniel – ONC – Director Office of Policy & Research
The statute doesn't give a timeline. There's nothing specifically locking us into a particular timeline. With that said, we're feeling a lot of pressure at ONC to do those quickly, because we are trying to make sure that there's some regulatory structure governance mechanism to connect with the meaningful use stage one.

Our timeline is as soon as possible. We're talking sometime in the year 2011 to have a draft of a proposed rule, but we don't have a specific time table that we are willing to commit to at this point.

Jim Borland – SSA – Special Advisor for Health IT, Office of the Commissioner
If I could, Paul, just a quick follow on, and this is more specific to one of the slides. On slide 19, your second recommendation, can you explain what you mean in the third bullet when you talk about a defined security level of assurance?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
The origin of this is that we saw it as necessary to step back from the tendency to use the terms privacy and security as being the same thing. That there's a component of security that's necessary to assure privacy, but there are other aspects of security, data retention and so forth. So when we talk about that, it's really saying, what level do we need to assure that data is protected, not only from intrusion, but also from loss.

Jim Borland – SSA – Special Advisor for Health IT, Office of the Commissioner
Okay, I just wanted to make sure you weren't using NIST's definition of level of assurance or using it within that context.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I can assure you that was not what we were doing.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Latanya?

Latanya Sweeney – Laboratory for International Data Privacy – Director
So first of all, John, because I always expect great things from you. You certainly didn't disappoint. This is really good. It's really good. I have two questions, one very quickly is, on your slide on your sound principles, one of them is fairness and due process, but you didn't actually say whose fairness and whose due process. Do you mean all the parties or do you mean—? I love by the way, it's not patients, it's consumers, because I think at this level that's a much better construction. So did you mean consumers or did you mean providers?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
What we say in our document, which we gave you, we say that governance must operate in a way that is fair to those who participate in governance processes and those who are affected by governance decisions. So that when we talk about fairness and due process, because the governance is seeing how the system works, and it's to create an environment of trust.

Latanya Sweeney – Laboratory for International Data Privacy – Director
Right.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
So those entities that want to participate in exchange, if they are found not to be in compliance and are subject to a sanction, they should be treated fairly. So if one gets treated that way, another one gets treated the same way, and that they should have a due process. So it really was at a much higher level than saying, because the purpose of that is to protect individuals, whose information is flowing through exchange.

Latanya Sweeney – Laboratory for International Data Privacy – Director
But not that the individuals will have the due process. Because see in some ways ... took that away, so I wasn't sure whether you were bringing that back, that the individual would have a due process. I think you answered it by saying, no, that's not what you meant.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
That's correct. At this particular level I think that that would be someplace else. That potentially could be one of the policies, which would be a product of the governance process.

Latanya Sweeney – Laboratory for International Data Privacy – Director
Then the second thing and that is somewhere in your thinking, I think you should really survey what are the architectural paradigms. Because they totally change the formulas in your thinking, depending on seeing some of the fantastic things that are lightweight, but possible.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Okay, David Lansky?

David Lansky – Pacific Business Group on Health – President & CEO
It's wonderful, John. You've come a long way in this really tough area. My question might be a communications issue or kind of wrapping my head around the question of authority and enforcement. I'm going back to slide 8, where you have the definition of the nationwide health information network in quotes. You note that that entity is a way to exchange information through the HIN, which needs to demonstrate compliance with a set of requirements of the precondition. We know that the HIN is a set of the standards, services, and policies.

I understand there's an opportunity to propagate this, define the standards, services, and policies. But I have a hard time with knowing what the "it" is, which has authority to enforce, other than through contracts. If it's a contractual participation or is it a matter of is it self-enforcing? Because some of these mechanisms of data exchange are self-enforcing. You can't do it if you don't match the standards and so on or if the other party won't communicate with you, or is it enforced through, and you mentioned in here in the notes, so there's a complicated regime already in place of enforcement that's multi-layered.

So I guess my question, which goes back to your first point about what the HIN is, is what's the it? How would the process work from here forward to clarify what the "it" is? An example with NHIN Direct, you can imagine a variety, it means a direct exchange of information that sort of bypasses this it, because it uses the Internet and it uses some data standards and exchanges information. How do we start working towards an understanding of what the "it" is and how something enforces compliance with the standards, policies, and services that are part of that it?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I think I'll go back to the basic principles of engendering trust and facilitating interoperability. We look at using the health information network, exchanging through that as being a seal of approval of some sort. So if I'm a patient, at some point if we do this right, I'm going to ask my provider when I get that notification that my health information is on the way to somebody else, I'm going to say, "Is it going through the seal of approval mechanism? Is it going through the HIN?"

My answer of approval may be one or the other, depending upon my concern about privacy, my individual concern, my understanding of the system, and whether or not I'm willing to take the risk of my personal health information going through a mechanism that hasn't gone through this governance of process and approval. So I think that's what we're conceptualizing that there is some way of saying that this entity is following the policies and standards and a system of governance that we're recommending and that looks to assure trust. That not only, I as a patient, but as I'm a provider trying to protect my patient's information. I know that my partner, who also has the field, is a trustworthy entity we exchange with.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Okay, Deven?

Deven McGraw – Center for Democracy & Technology – Director
A quick one in terms of the open questions you've got, what is the role of ONC in governance? Recognizing that we are all, a committee and all the workgroups underneath of it, our primary role is to provide recommendations to ONC. But with respect to many of the legal framework and the role that government plays, it's not just ONC that plays a role here. You've got the Office of Civil Rights, who enforces HIPAA on the privacy and security side. You've got privacy and security rules for substance abuse treatment facilities. You've got CMS, which actually sets the meaningful use criteria, although, working in tandem with ONC.

So I guess I would just suggest that if you're thinking about what's the appropriate role of government, that you might broaden the lens a little bit, notwithstanding that the recommendations to come rest at ONC door. I think you have an opportunity to think about the role that government plays in governance.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Thanks. Gayle?

Gayle Harrell – Florida – Former State Legislator
I just wanted to add one comment about the good housekeeping seal of approval is kind of the concept you're using. That these are governance models, that if you use this framework, then you meet that good housekeeping seal of approval. I think that since we are spending public dollars, a good deal of public dollars, we want to make sure that any of our certified products or our HIEs that are being funded by the federal government and taxpayer dollars, meet that standard, meet that seal of approval.

Then I as a patient can be secure in knowing that my information is going to go through an entity that meets that approval. I think we have a public responsibility here to make sure that any dollars that are spent, that are public dollars, go through that and meet that. They should not receive dollars if they don't.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Absolutely. Obviously, this branding of an entity that has met the standards to use exchange for their health information network becomes a vehicle through which the largest health insurer in the world, CMS for instance, could use that as a standard for how they reimburse. ONC and other entities that are giving grants can determine whether or not those grants. But it's not just a vehicle for the public sector, it's also a vehicle for the private sector.

I believe that so much of what exists in exchange is not going to be sustainable unless there is significant private sector involvement and funding of those mechanisms. So it leaves an architecture that the private sector can use to create that platform. Once you have a certain set of standards and you know what the policies and procedures are, that gives you room for innovation, as long as you don't do it so tight that you say you have to do it in a cookie cutter fashion. But you don't compete on how you protect privacy and security, you compete on how you implement the protection of privacy and security.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Jodi?

Jodi Daniel – ONC – Director Office of Policy & Research
I lost my tag, so I'm Deven, no. I just grabbed one from there. Actually, this conversation was exactly what I was going to add, is that I think— I'm not speaking from an ONC's perspective, but more from my own. How I've been thinking about this and talking with folks in the workgroup, and wasn't sure how we were going to do this, is that there are levers that we have. That if you have a set of policies, standards, enforcement, etc., that build trust and interoperability, and people want to exchange with folks that they're not used to exchanging with, that they're more likely to use it, because there is at least an established level. There is that good housekeeping seal of approval.

Then we do have these other levers to make that happen. We are giving out a lot of grant money. There is a lot of federal data that folks want access through the VA, CMS, through their requirements and meaningful use. I think there are a lot of different ways of encouraging folks to want to get that good housekeeping seal of approval and to want to exchange through this HIN. Although, I don't think that there is any expectations, this will be the only way that folks can share health information. So looking at this as a preferred option, but one that we think folks will prefer for a whole host of reasons, both public and private leverage.

Gayle Harrell – Florida – Former State Legislator
... and it occurs to me that one point of clarification is a miner issue of copy editing. On the bullet that David specifically raised, an ... condition to using the HIN. As you know that standards and services are going to be in the public domain, anybody can use them. So the copy editing that would have made that a lot clearer is to use the HIN brand. By the time you set up the rest of this structure that enables you to say which are those recognized policies, standards, and services with a minimum level of security, and you've got your compliance, your validation mechanisms in place that you can test that with.

Then people have two choices, they can go ahead and use them without bothering to go through the validation mechanism, and they're free to use them, and we hope they'll work, and they can use anything else. On the other hand, if they choose to use them and would like to have the brand, then there will be this extra level of validation that, and clearly, we hope it won't be too burdensome. What we're sort of hearing is that there is actually interest from the field and looking for this, just as they've always looked for standards. It doesn't seem to be a negative motion.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Larry, final questions?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
Let me build on this notion of that this governance model might apply to other exchanges, not just the envision of health information exchanges that are the state supported quasi governmental ones. But Kindred's seeing a lot of requests for us to share information with other providers. There seems to be a growing model of large providers creating in effect their own health information exchange organization centric around their service network, and then bringing in all of their supporting players.

So to have governance that was some level of consistency here would be really great, because we're seeing huge variations in what people bring to us as agreements. Some of which are very, very minimal,

and kind of you've got to be kidding. Others of which are clearly thought out and have a true governance model going on.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Great, thanks for great work, John. Mary Jo, and now I think we'll open it for a public comment, please.

Judy Sparrow – Office of the National Coordinator – Executive Director
Yes, we would like to invite the public. If anybody wishes to make a comment, please come up to the microphone in the room, queue it, and if you're on the telephone, you can press star one to speak, or if you're on your computer, please dial 1-877-705-6006, and I'll ask Carol Bickford to begin.

Carol Bickford – American Nurses Association
Carol Bickford, American Nurses Association. This is in relation to the presentation, Paul, that you did, in relation to the workgroup report out. I was struck by two items in relation to the patient engagement information sharing slide. One is, where is there a mechanism for us to incorporate the healthcare plan into disciplinary, into professional, and includes the patient participation discussion? Because you were talking about discharge instructions, visit summaries, the clinical data of repository, those sorts of documents, so that's one piece.

But also, I'm struck by the fact that we don't have a mechanism to encompass an identification of the team, who that is, and some mechanism to engage for recognition of that communication, that partnering, that sharing, including the patient in that population. Your workgroup may have had some discussions about that, but I would invite you to consider that, particularly in light of the testimony from yesterday's NCVHS subcommittee.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you, Carol. Ms. Spiro?

Shelly Spiro – Pharmacy e-HIT Collaborative – Director
My name is Shelly Spiro and I have a set of similar comments, individually at the different workgroups, the Policy Committee workgroup and then also the standard committee. The first one, I'm addressing the Policy Committee as a whole. As I said before, my name is Shelly Spiro and I'm the director of the pharmacy e-HIT collaborative. This is a newly formed collaborative of nine of the professional pharmacy associations. Our organizations represent over 250,000 members, with our pharmacist practicing in all different practice settings, hospitals, communities, long-term and post-acute care settings, which include school nursing facilities, hospices, home care, the community setting, ambulatory clinics, universities, and it's not excluding any area.

The collaborative is focused on ensuring the technical standards are aligned with the nation's growing need for an all-inclusive clinical services, provided by pharmacists in all of these practice settings. The services provided by pharmacists, especially administering and providing immunizations and medication therapy management are integral to all providers using the electronic health record in a meaningful way.

Pharmacists play a key role in the prevention of adverse drug events, medication reconciliation, and to ensure medications are safely used in all of these practice settings. The pharmacist's electronic health record has been developed. It's been validated through both NCPDP, which is the National Council for Prescription Drug Program, and also HL-7, Health Level 7. In the near future, we'll be going through the certification process.

Pharmacists have the ability to move past the record keeping of the aspect of just prescription processing to a fully integrated clinical electronic health record. The pharmacists electronic health record will integrate with other providers electronic health record and also the patients electronic personal health record. To assure the practice improvements provided by pharmacists related to safe medication use is definitely achieved.

The collaborative has pharmacist members involved in the state HIEs and also the original exchange centers. But on all of these initiatives, we are collecting information of which pharmacists are involved in that through one of our members, NAPSA. the National Alliance of Pharmacy State Associations. Also, we're definitely willing to assist the Policy Committee in anything that we can do to help with the bi-directional exchange of clinical information outside the prescription process. I thank you very much for the comments.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you. I believe we have a caller on the phone, if you could please identify yourself, your name and organization.

Tom Leary – Healthcare Information and Management System Society – Director
Hello, this is Tom Leary with the Healthcare Information and Management System Society, HIMSS. I wanted to specifically thank Dr. Blumenthal for his comments earlier today to suggest that the HIT Policy Committee collaborate with other activities at HHS. Particularly, the national healthcare quality strategy and plan effort that's underway. We've put in comments to HHS in the last week suggesting that a collaboration rather than one all whether it's at the state level or at the federal level. The collaboration will improve the possibility of our members meeting the requirements and being able to meet the metrics that will be identified. The other recommendation is that you work closely with the national priorities partnership that's underway through the national quality forum. Thank you.

Lindsay Hoggle – American Dietetic Association – Private Consultant
My name is Lindsay Hoggle and I'm a private consultant. I'm here today on behalf of the American Dietetic Association. My comments are in reference to this morning's discussion on the Quality Measures Workgroup. Thank you for all the considerations that you've put out there.

I wanted to just provide a few perspectives from the standpoint of understanding the pressure that this committee and ONC is under to provide a continuous improvement and layer some quality measures with each stage. Ask that I really think if we can take the quality measures that are there and just increase the percentages that we have, it might allow providers a time for stage two to catch their breath, for us to focus on consumer engagement a little bit more.

To also encourage other providers to adopt EHRs with the realization that you have a moment to catch your breath, make changes, do some risk analysis, and risk mitigation, particularly with the timeline that we've got in terms of just hearing today in terms of vendor design and development. There's some concern that this huge workflow change for all of us, including consumers. Consumers are not used to having all of their data in front of them. If they do get it electronically, they may not know what to do with it. Just kind of a plea for that from the standpoint of safety and also looking at the quality measures long term. Thank you.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you, Lindsay. And last comment, please.

Chantal Worzal, AHA
Good afternoon, ... from the American Hospital Association. I really want to thank you all for a very, very thoughtful conversation. They're clearly challenging topics. You all have shown tremendous stamina and commitment in staying with it.

Some of the themes that I heard that I thought were very important were a commitment to evaluate and learn from early experience on the ground. A recognition, the need for a realistic timeline moving forward, really a need for an approach that allows providers to use the power of the EHRs to meet local needs. That's something that I thought was a little bit new today. They do have local priorities for quality improvement, for care coordination, for patient engagement, but they want to use the EHR to support.

Also a commitment to put your work in a broader context of those existing regulations and changes that are coming down the pipe with health reform. I want to just give you some examples of that broader context in the hospital world. It is complicated and rapidly changing. Today, more than 98% of hospitals quarterly report 40 or more quality measures to CMS. Those are all publicly available on the hospital compare Website. So quality reporting is not new for hospitals.

It's very important that the quality measures that are used are scientifically valid and reliable. That data collection results into something that we know is comparable from one provider to another. If that is not the case, providers won't want their quality results used. They won't think it's fair. So that is the context that you need to take forward into future quality reporting efforts, which include and the hospitals fear, starting in fiscal year 2013, which does start on October 1, 2012, a significant payment penalty for the 25% of hospitals with the highest readmission rate.

This was in the healthcare reform law and will be operationalized by CMS. This also includes a value-based purchasing program that will put a significant chunk of hospital payments at risk for actual performance on specific quality metrics that are being worked through by CMS in consultant with the field as we speak. So as those things are going on, it's clearly very important that the conversation about quality metrics for meaningful use be aligned with these other programs.

On that quality measure discussion, the quality workgroup is really covering almost an overwhelming array of measures that is both very, very interesting, and a little bit alarming to think about this vast number of measures that could be sort of coming down the pipe. But want to make sure that the workgroup is committed to paying a lot of attention to whether those measures are tested, validated, and pilot tested for operational use before they become part of the meaningful use requirements.

That's a tall order frankly, and there is an organization, the Joint Commission, that knows more than any other organization about how to operationalize quality measurement. I would recommend that this workgroup incorporate the Joint Commission in its deliberations. Thank you.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you very much. Dr. Tang?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Very good, thank you, and thank you to all of the committee members, and thank you to the ONC staff for continuing on this charge in all of this exciting and worthwhile activity. So thank you and see you in November.